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(54) **SILICONE RUBBER MALE EXTERNAL CATHETER WITH ABSORBENT AND ADHESIVE**

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See application file for complete search history.

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(57) **ABSTRACT**

The invention relates generally to external urinary catheters for males. More specifically, the invention relates to an external urinary catheter that includes an absorbent material to absorb urinary discharge. The absorbent material can be located in either a distal end of a tubular sheath, or in a receptacle that attached to the distal end of the tubular sheath. The tubular sheath of the external urinary catheter can include a tubular sheath of silicone rubber, wherein the sheath has an inner surface and an outer surface, and a layer of adhesive material directly and non-releasably bonded to the inner surface.

27 Claims, 9 Drawing Sheets

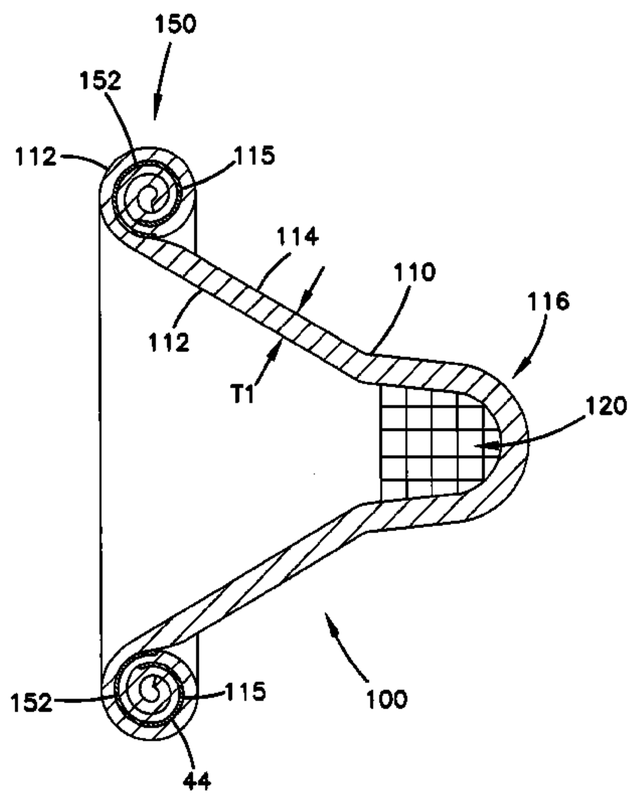

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FIG. 1

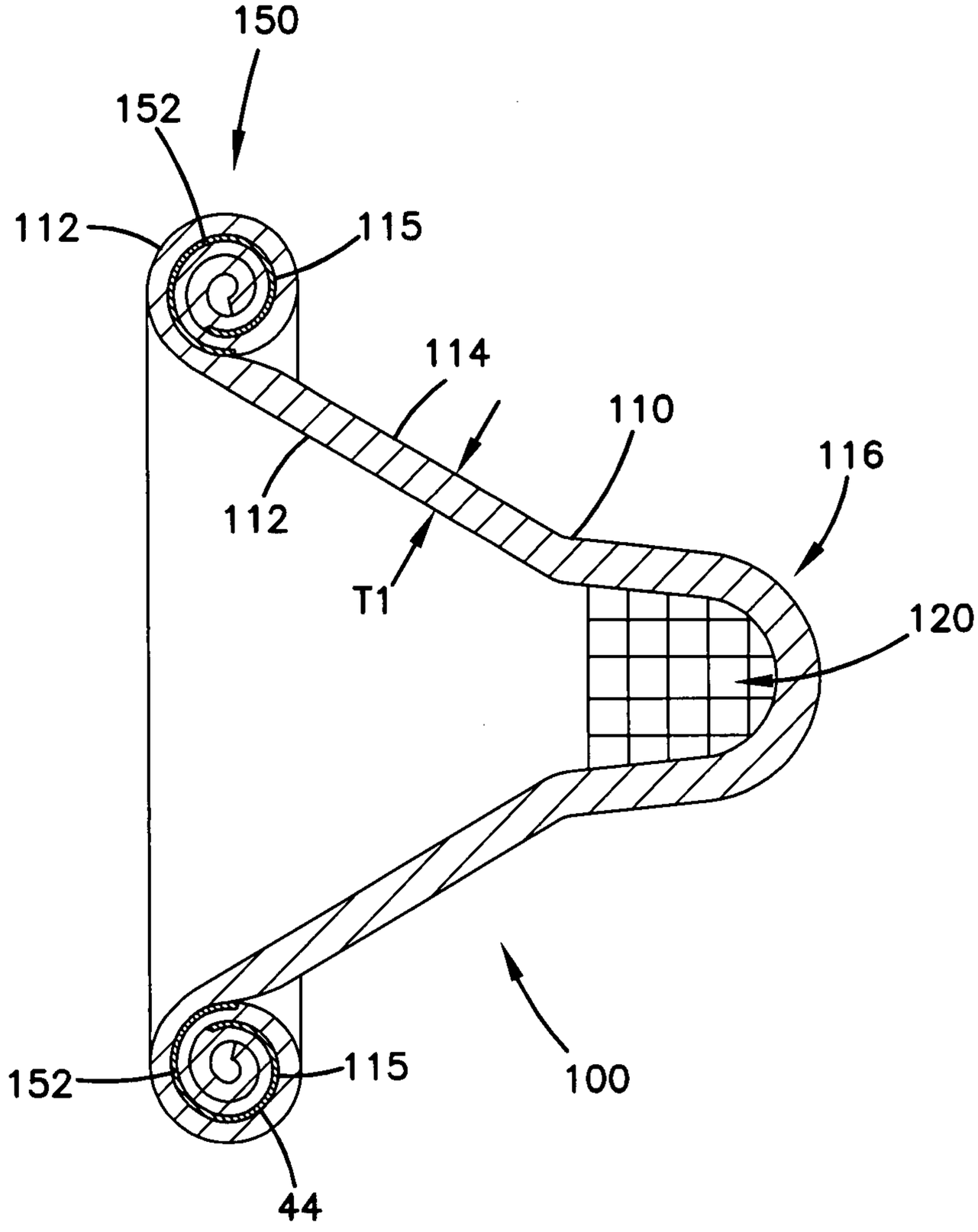


FIG.2

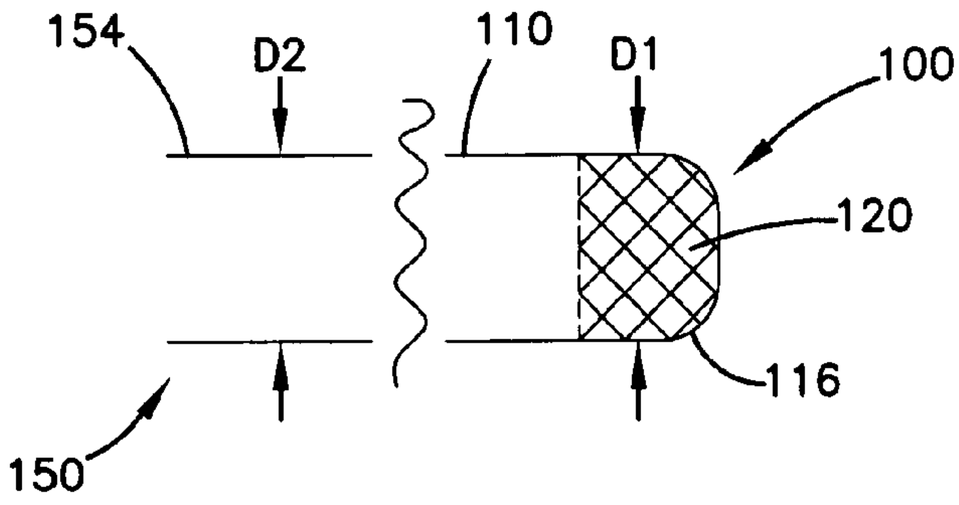


FIG.3

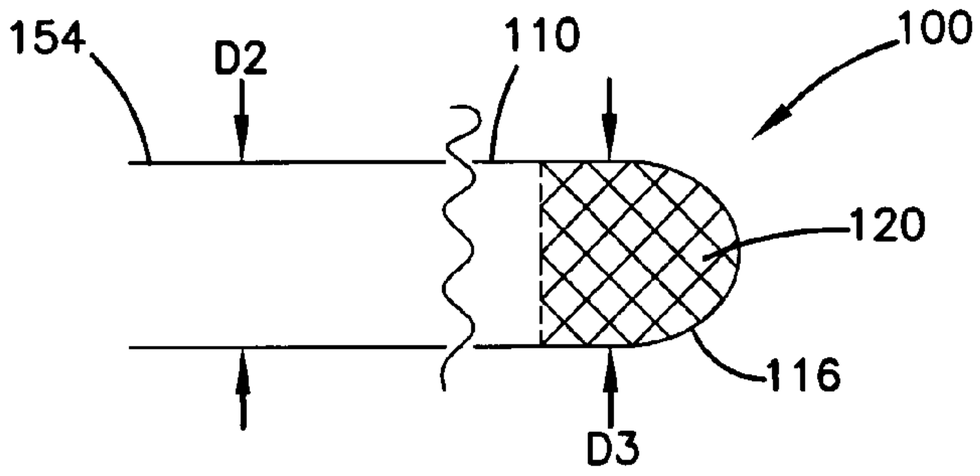


FIG.4

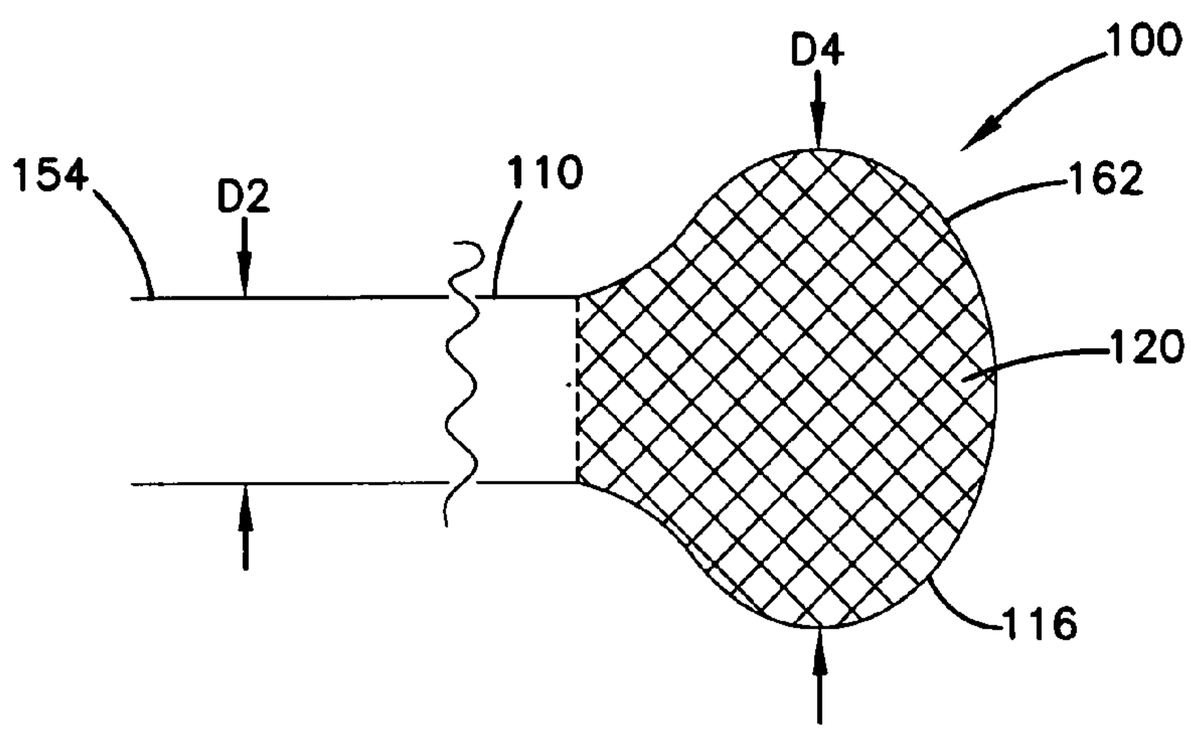


FIG.5

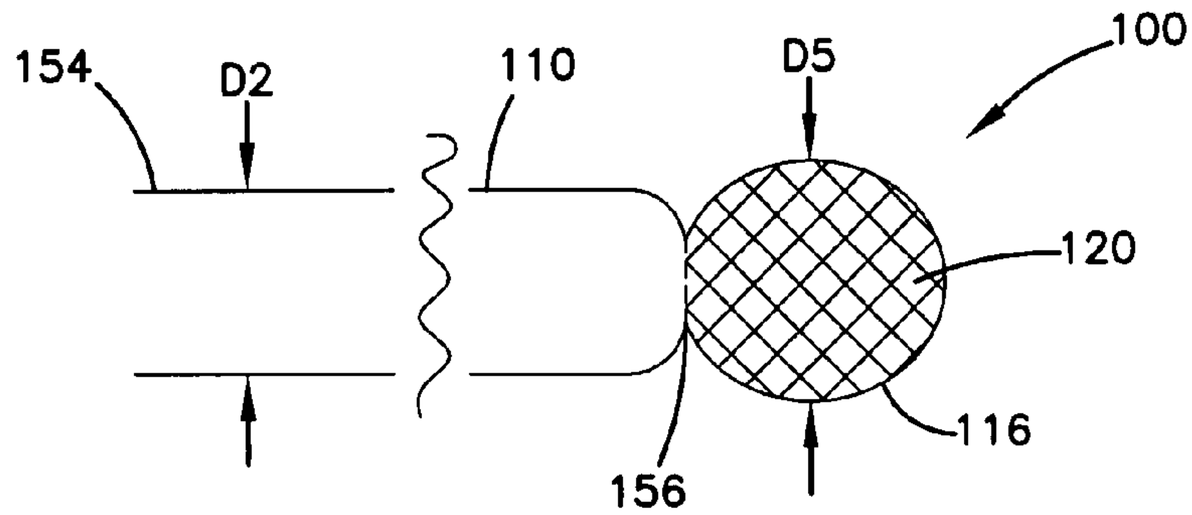
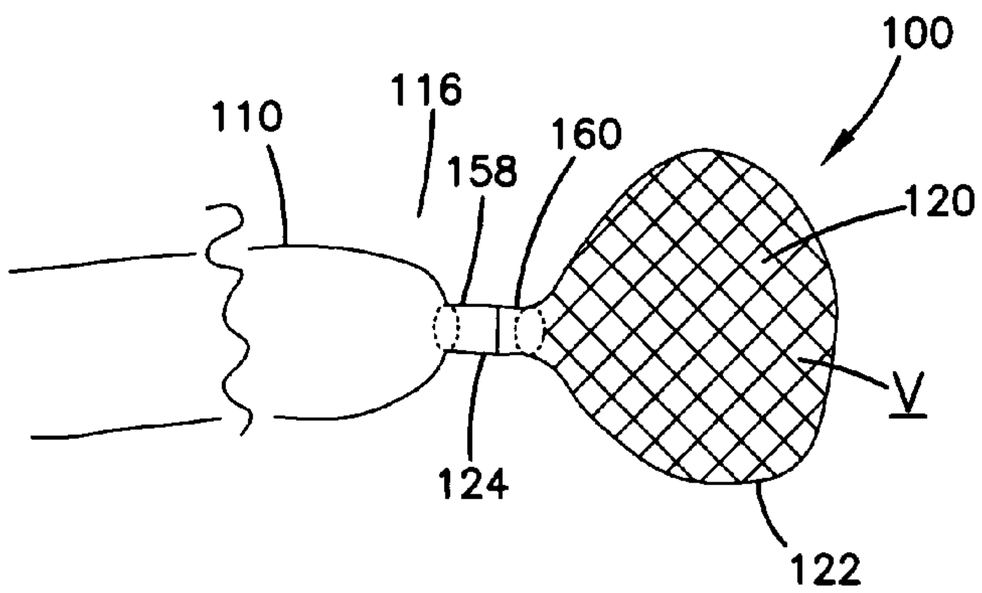


FIG.6



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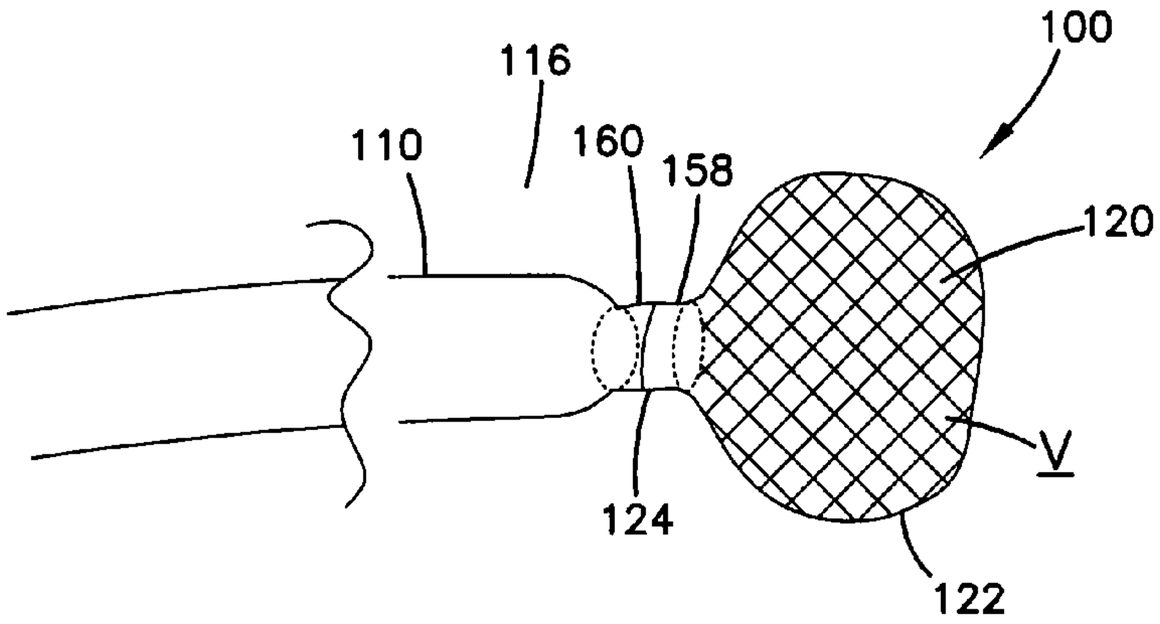
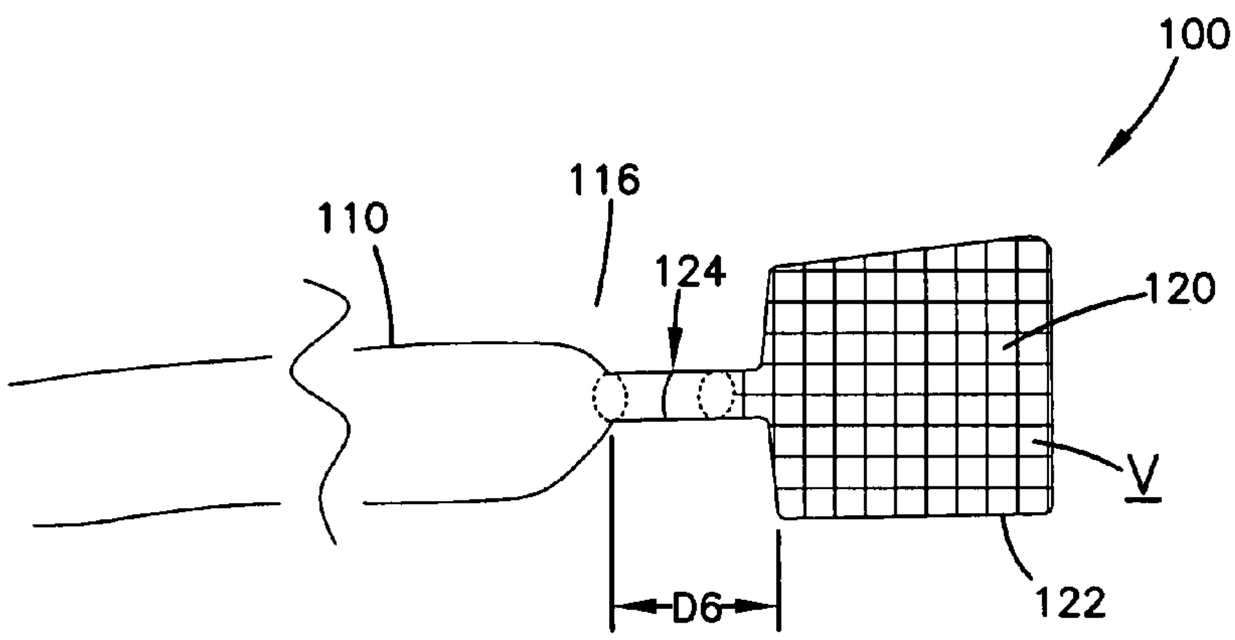


FIG.8



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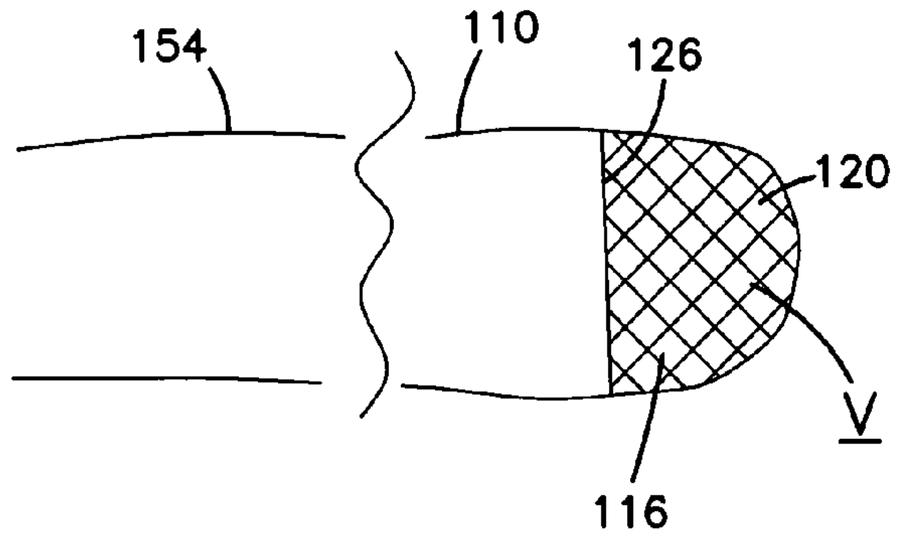

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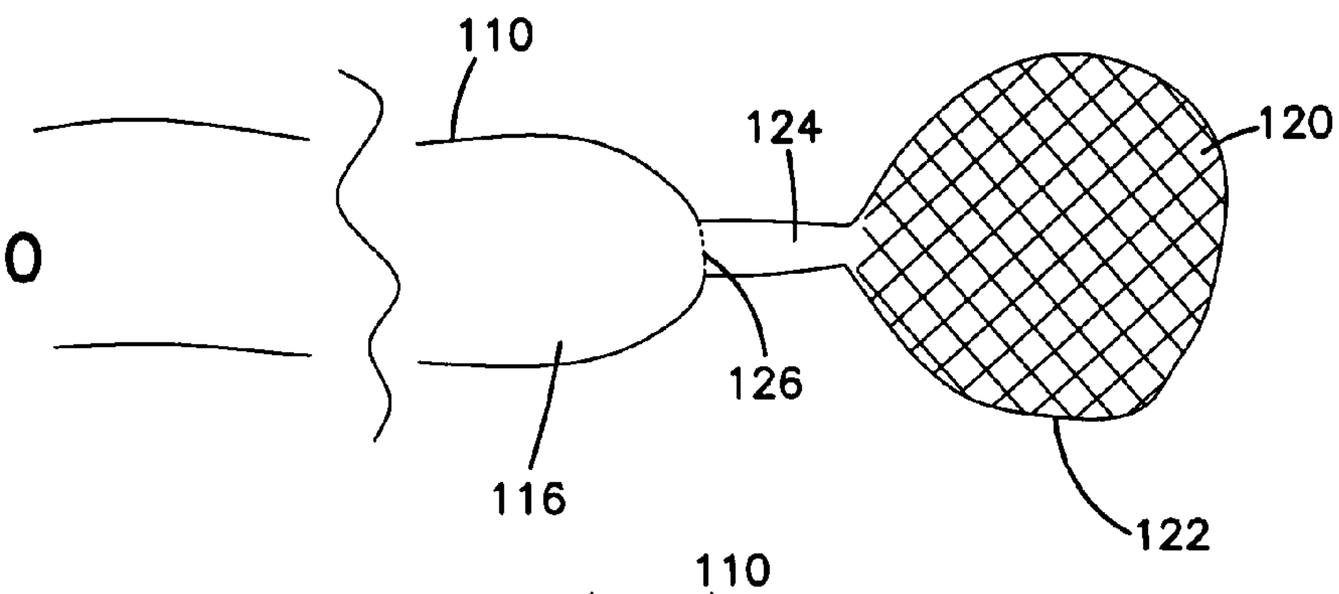

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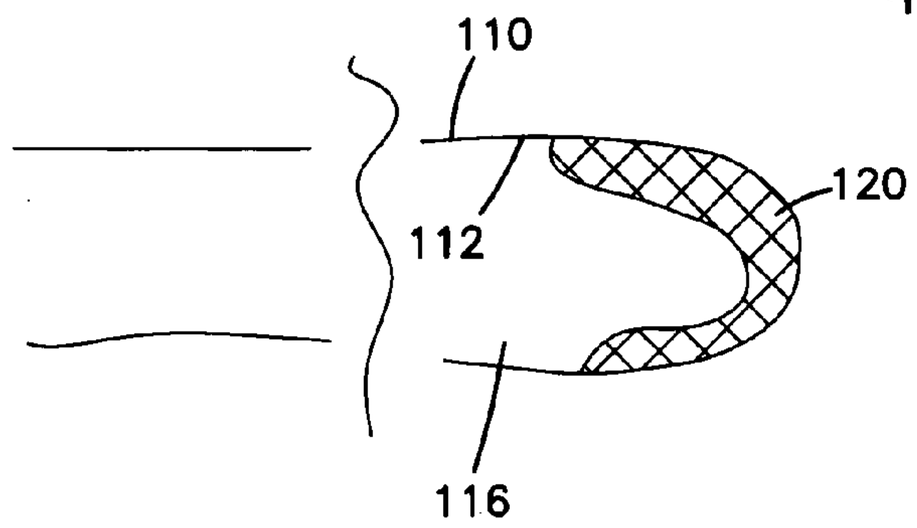
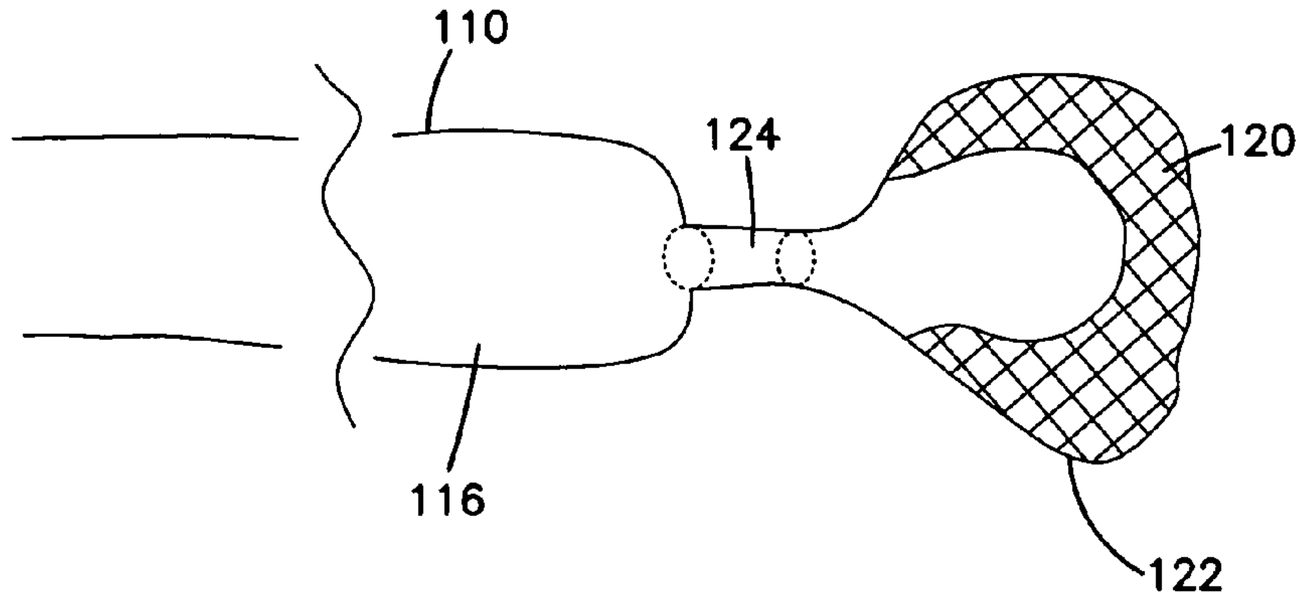


FIG.12



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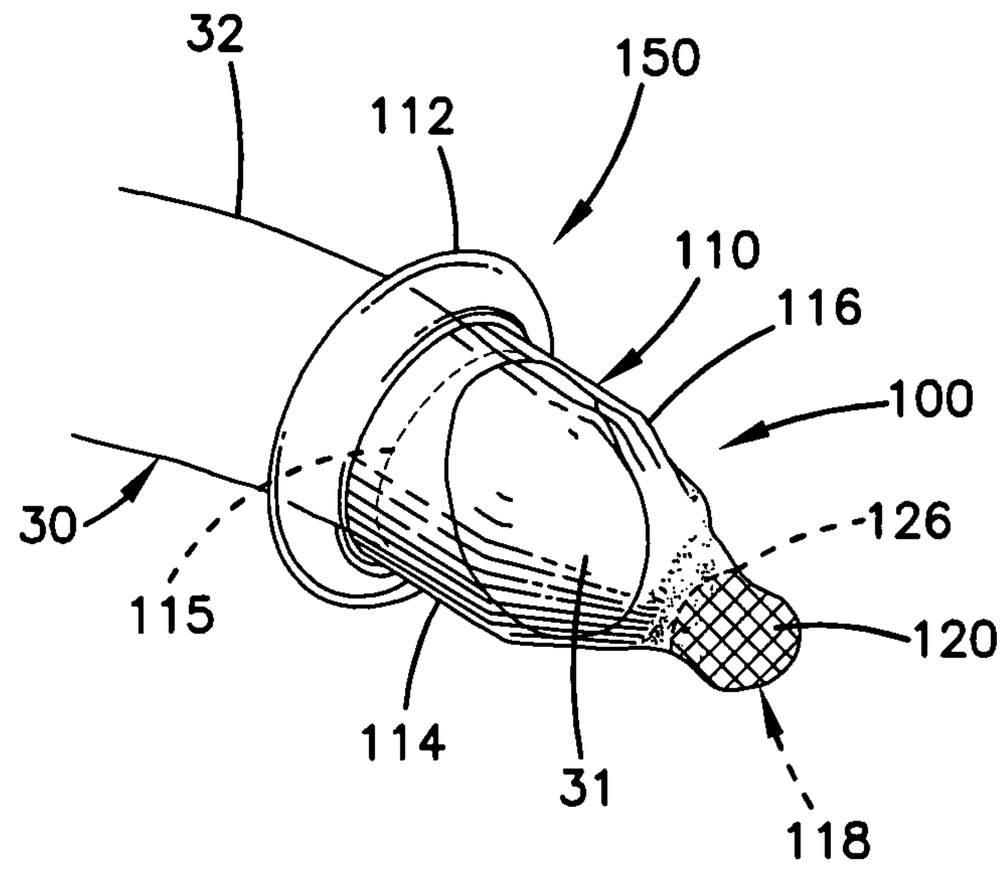
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110
116
100
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120
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118

FIG.14

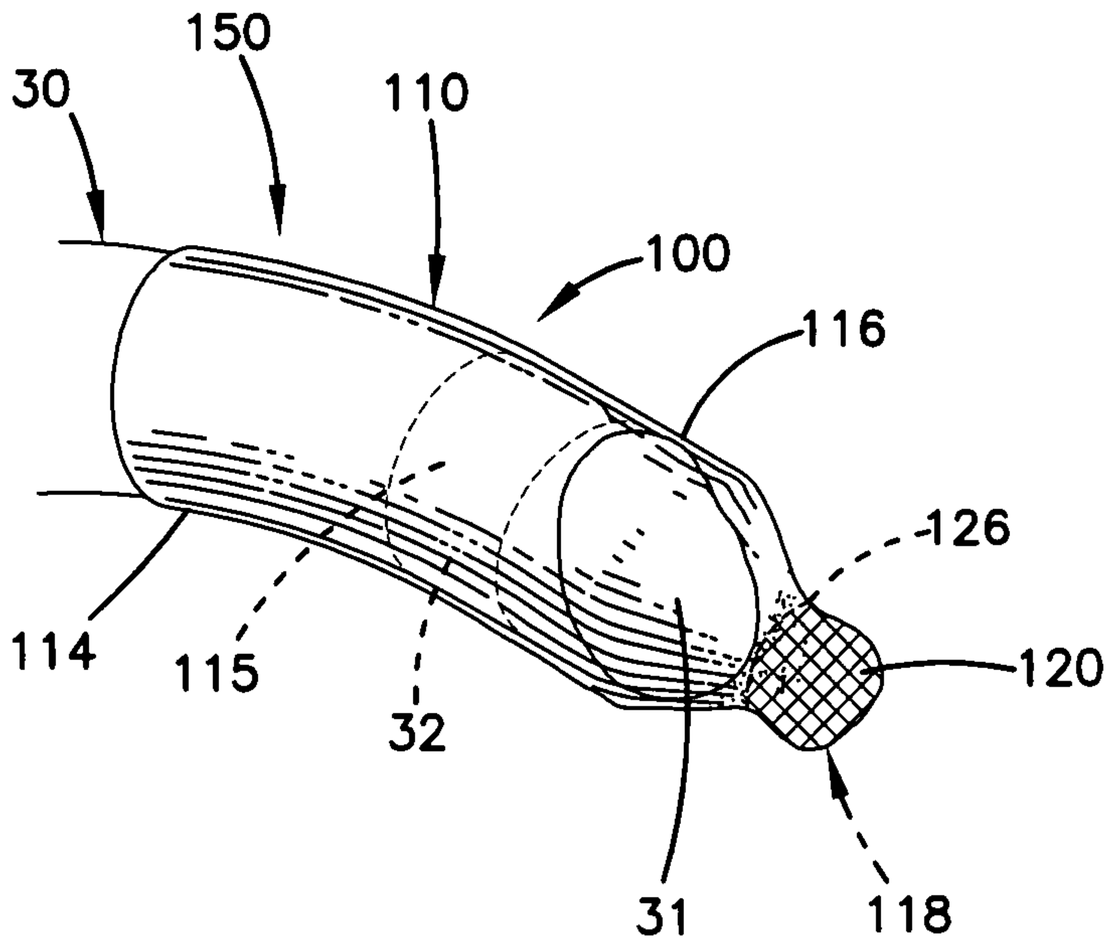
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FIG.18

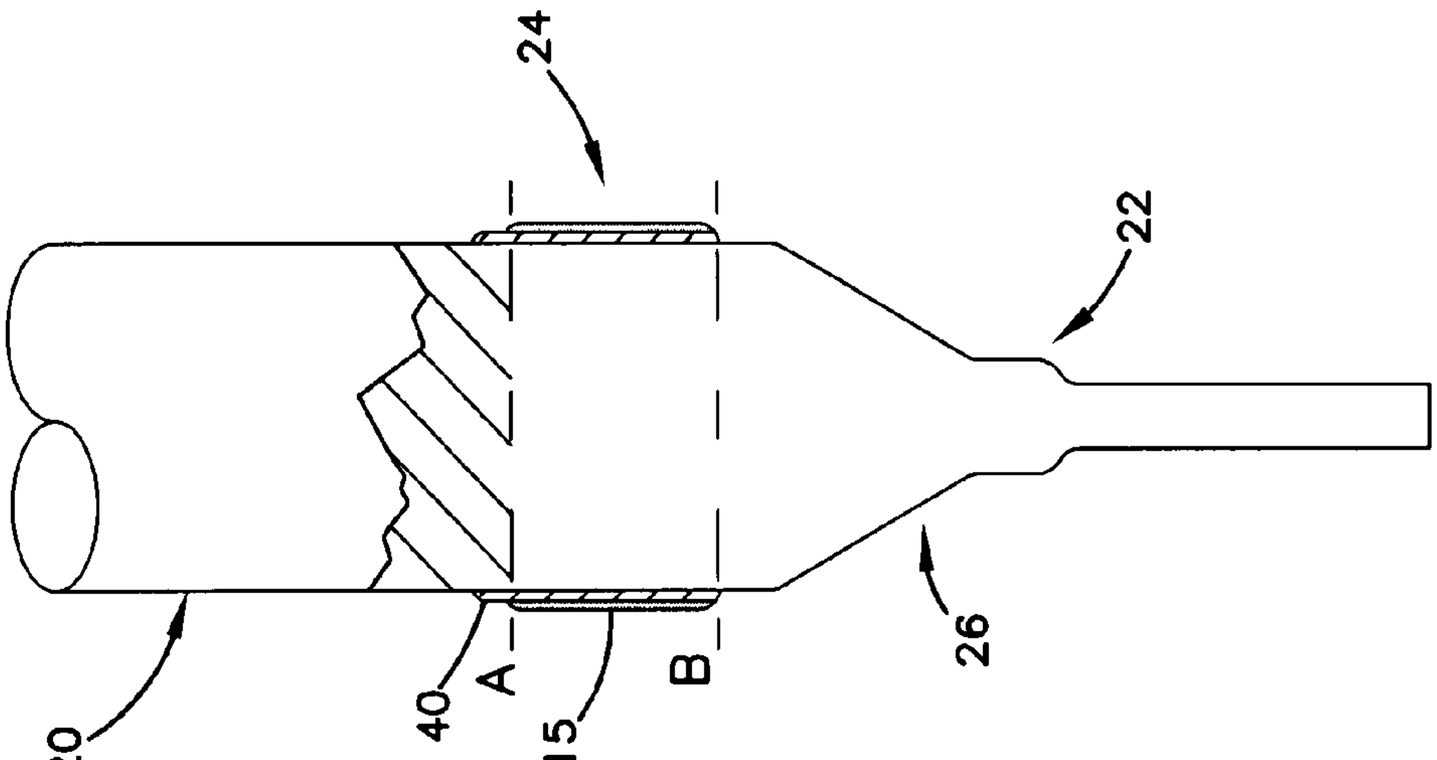
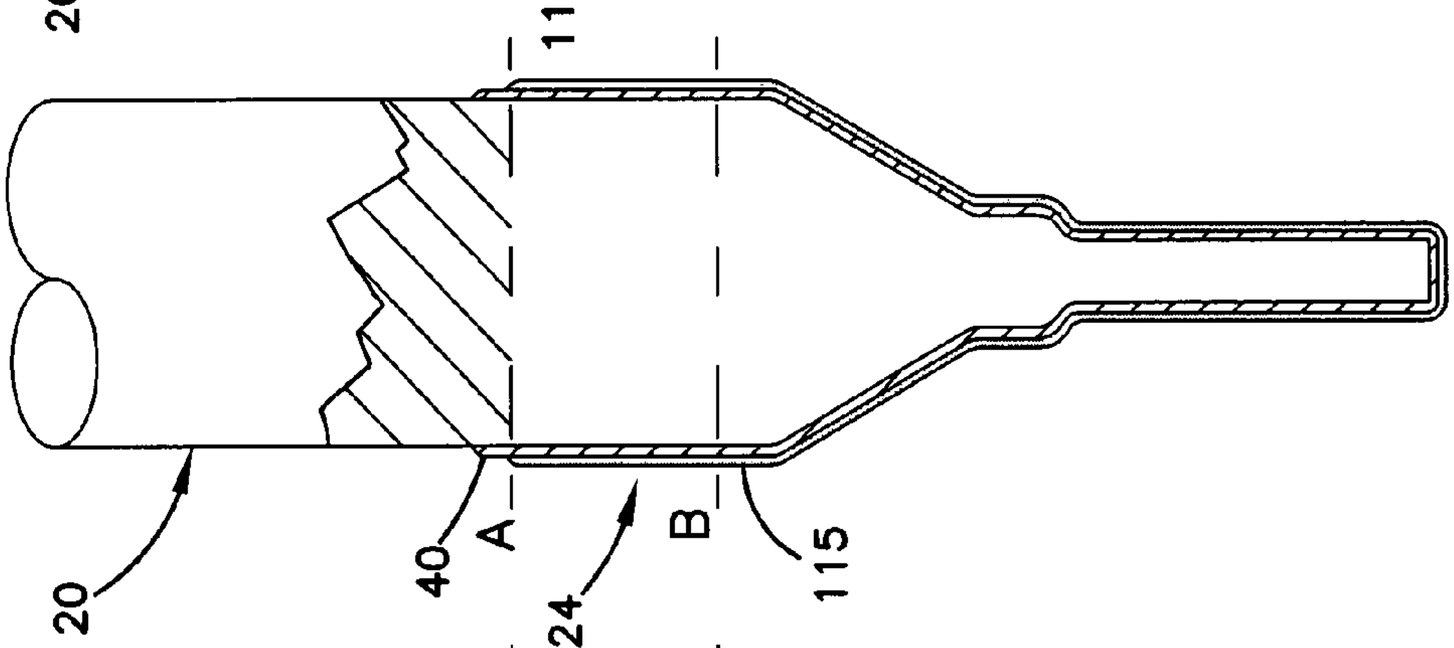


FIG.17



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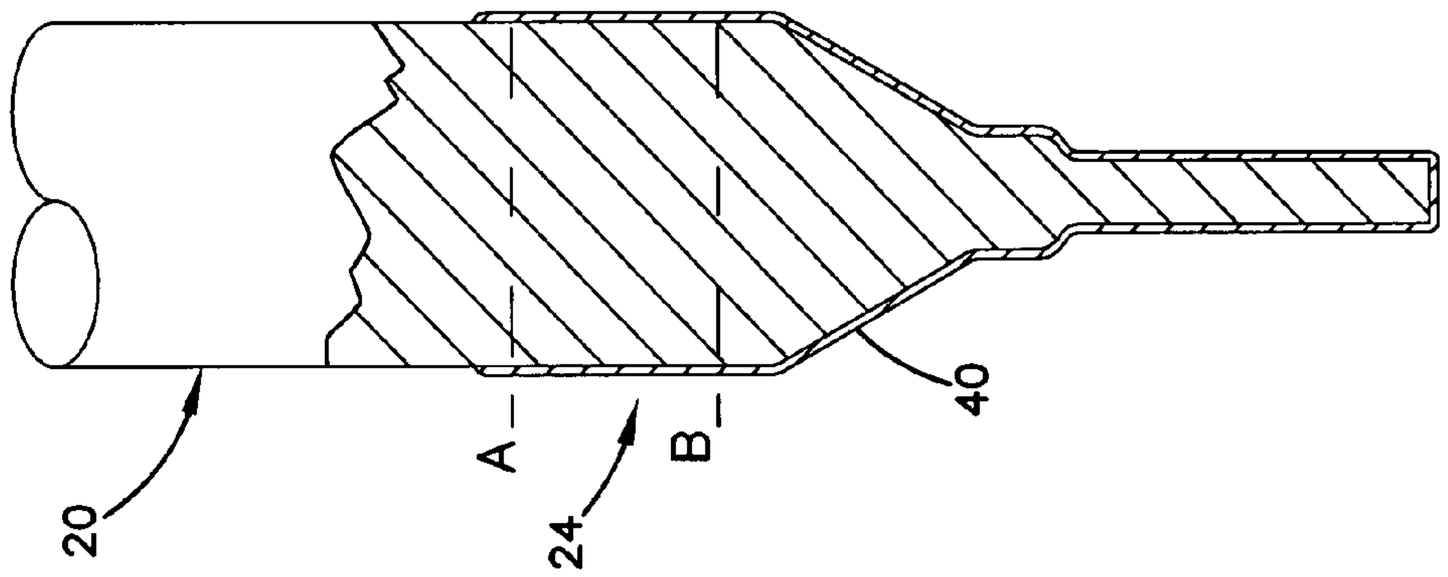
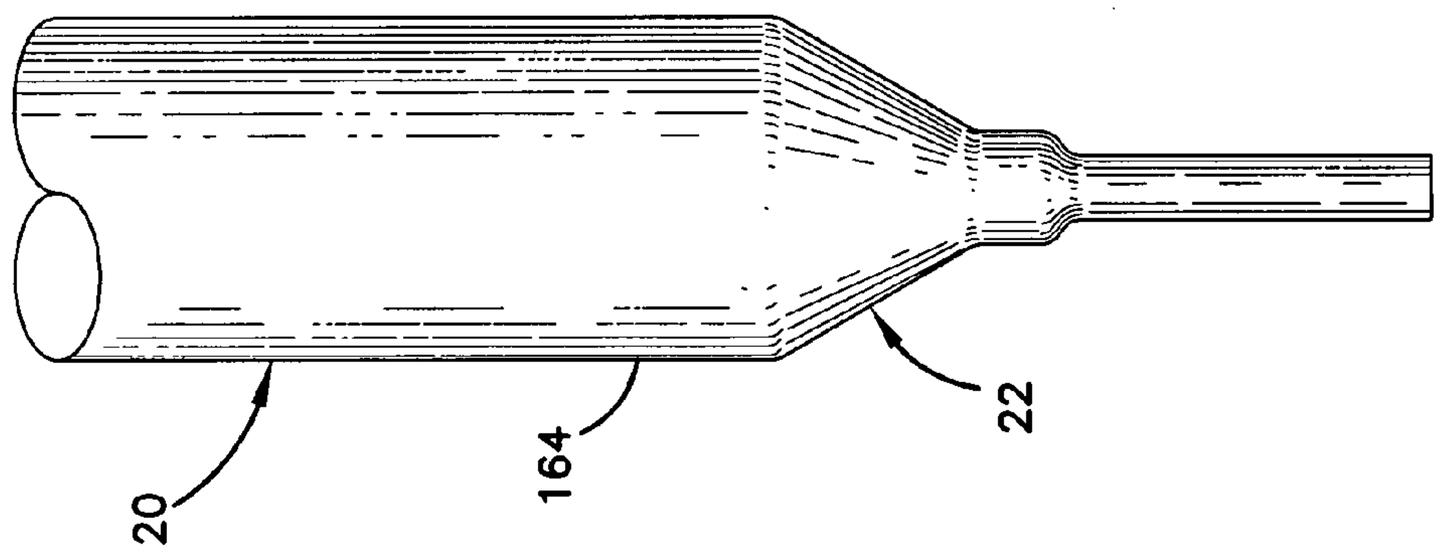


FIG.15



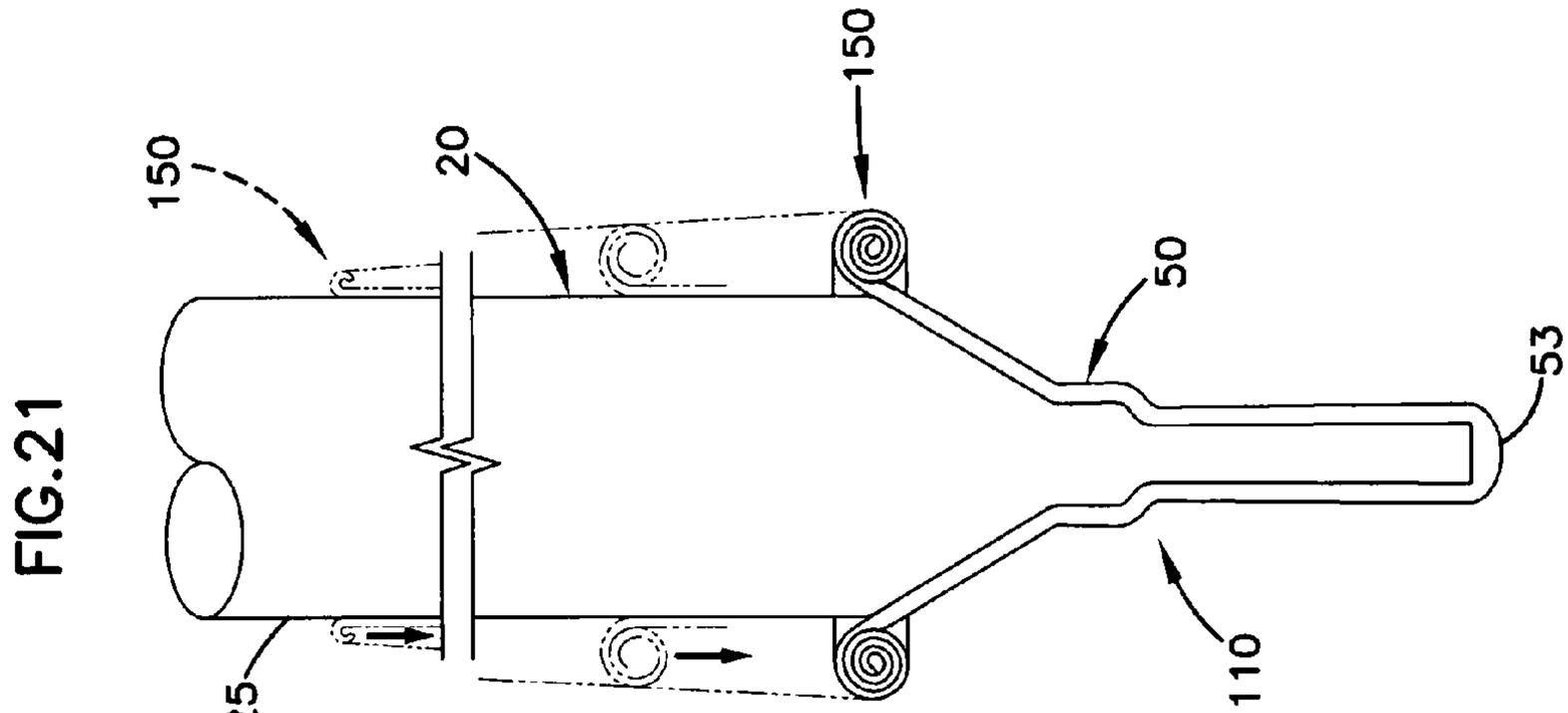
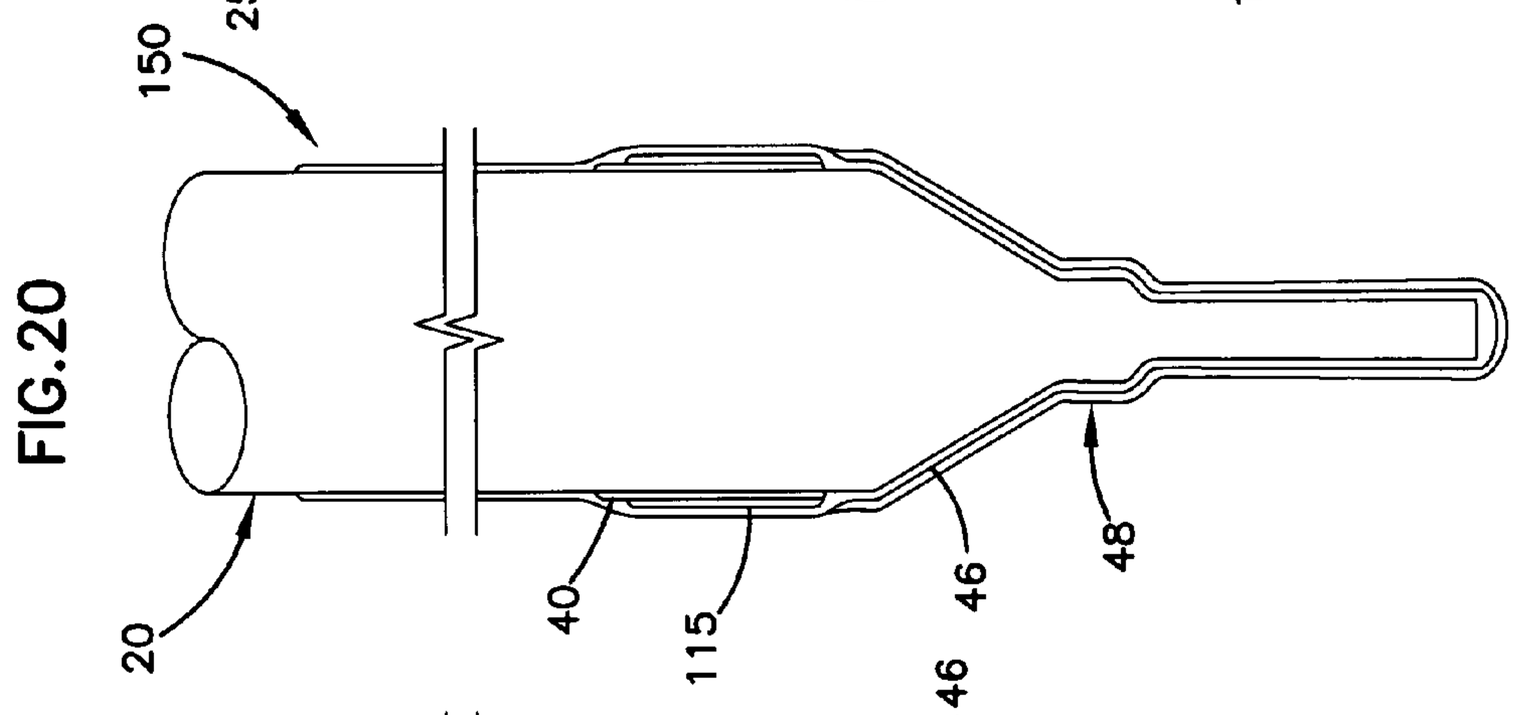


FIG.21



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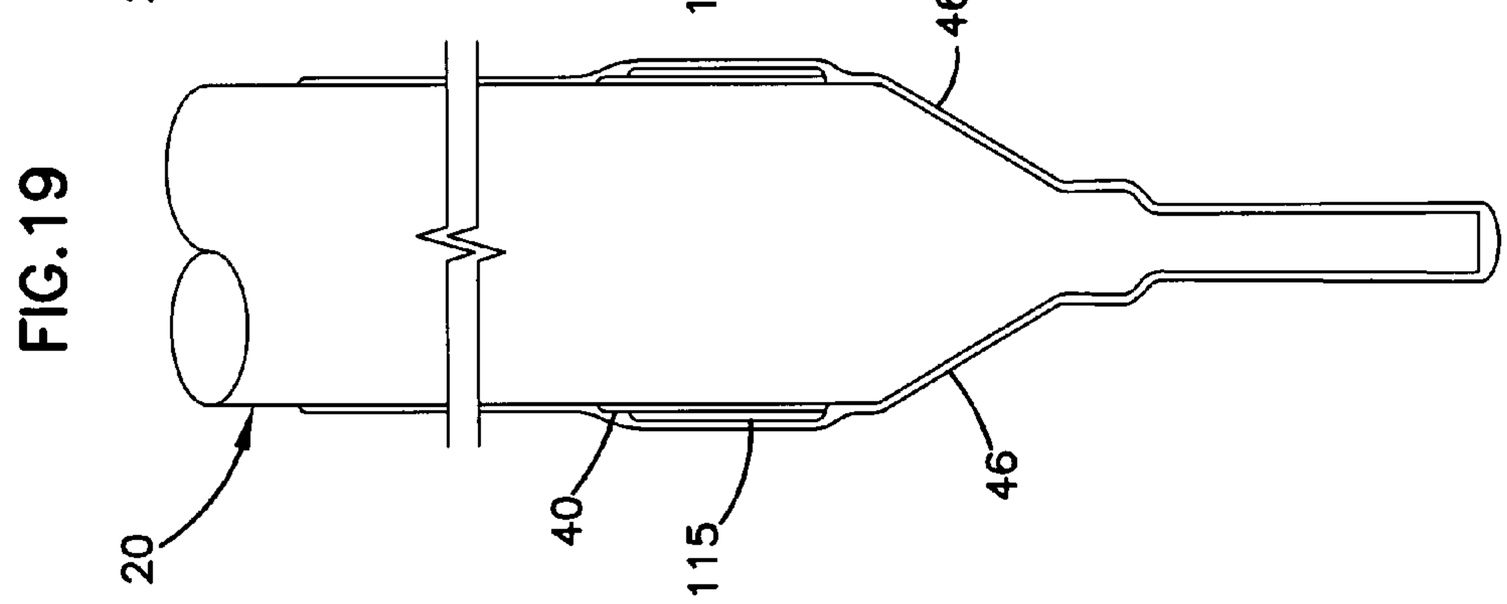
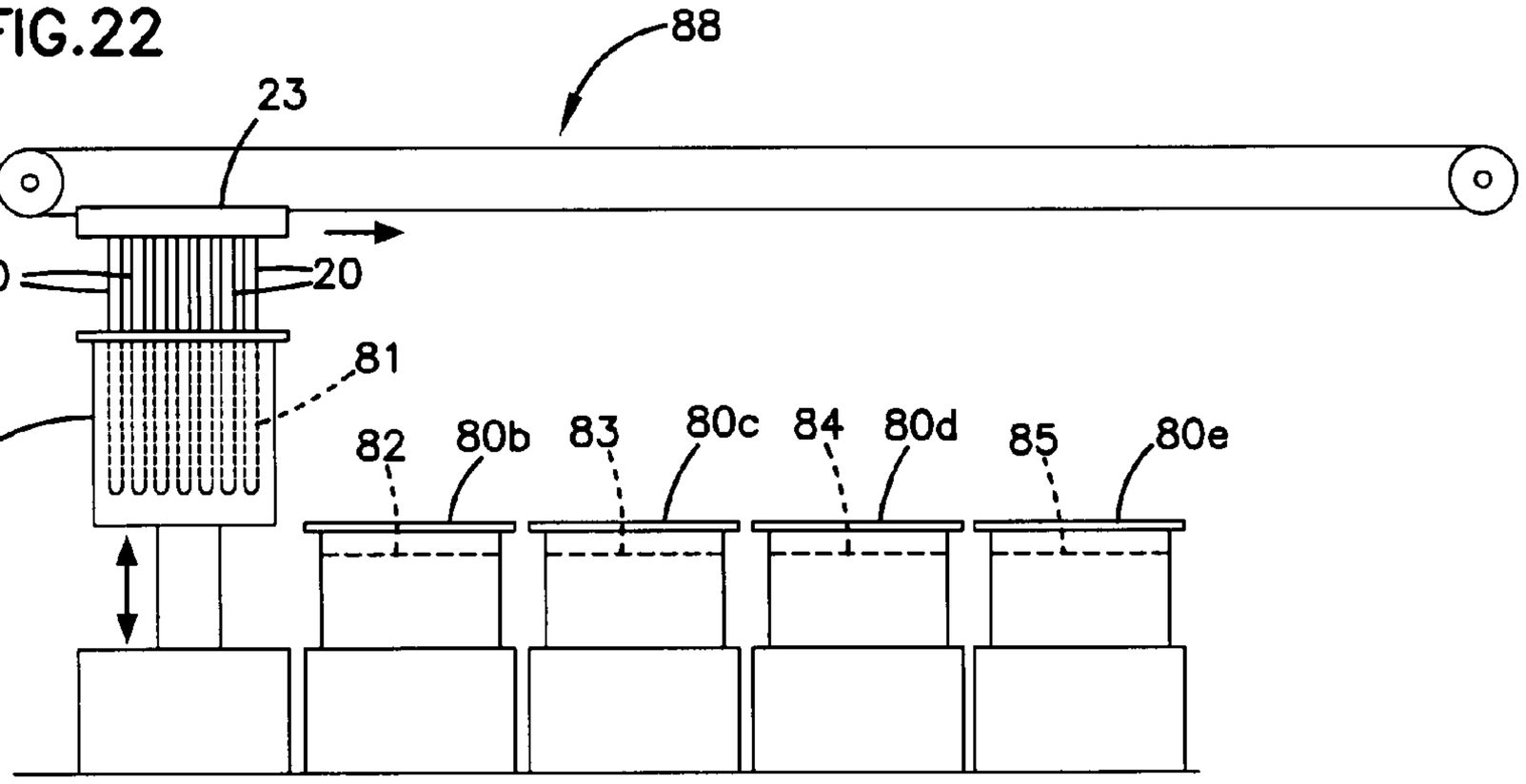


FIG.19

FIG.22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80b
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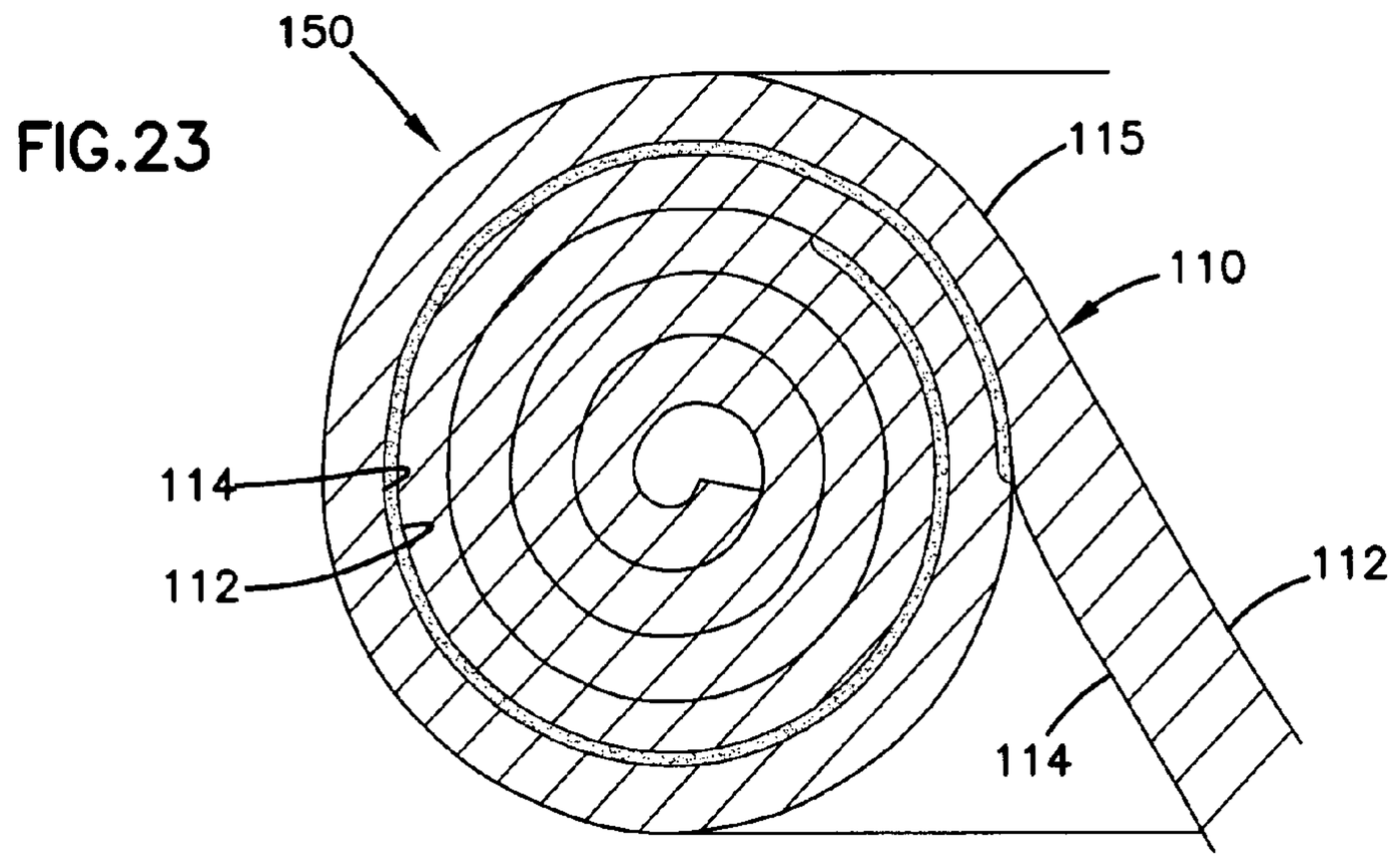
80c
84
80d
85
80e

FIG.23


150
115
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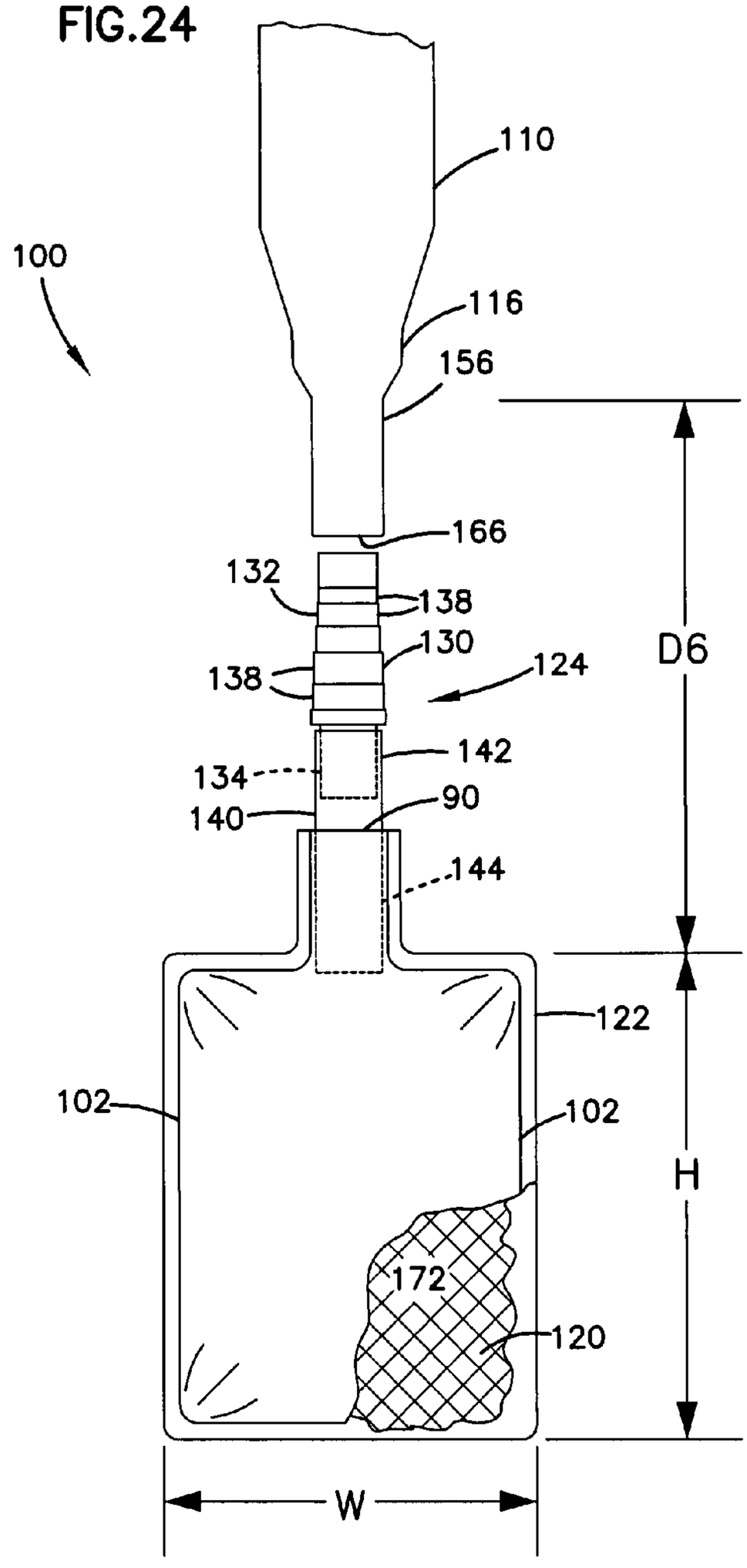
114

FIG.24


110
100
116
156
166
132
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D6
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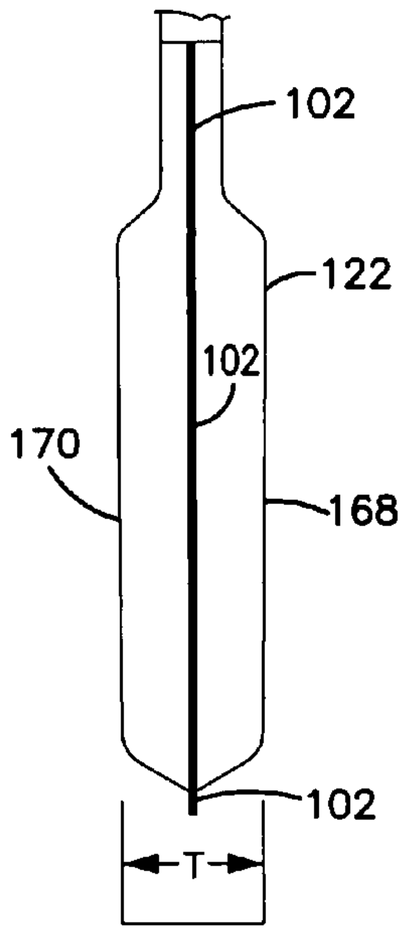
FIG.25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T

SILICONE RUBBER MALE EXTERNAL CATHETER WITH ABSORBENT AND ADHESIVE

TECHNICAL FIELD

The invention relates generally to external urinary catheters for males. More specifically, the invention relates to an external urinary catheter that includes an absorbent material to absorb urinary discharge.

BACKGROUND

Urinary incontinence can be a serious problem for men. Many incontinent men, particularly post prostatectomy patients, leak only small amounts of urine between normal voiding. Generally, male incontinence is handled through use of urine collection devices or absorbent pads. Urine collection devices include what is commonly called a "leg bag." A leg bag generally includes a tube and a large collection bag sized to collect an amount of urine typically discharged during voiding. The tube is retained near the urethra and extends to a location where the large collection bag resides. Often the large collection bag is strapped to the user's leg; hence the term "leg bag."

Existing remedies, although suited for individuals who leak a substantial volume of urine, are not well suited for an incontinent male that leaks only small volumes of urine between voiding. The existing devices are big, bulky, and uncomfortable. Other existing devices occlude leakage of urine, and are also uncomfortable. Some men will forego wearing such devices even though they suffer from urinary incontinence. Such men, and others using existing devices for the collection of only small amounts of urine, would benefit from a smaller, less bulky and more comfortable device that collects the small amounts of urine discharged between normal voiding.

Therefore, a need remains for a device that collects small amounts of urine leaked or discharged from incontinent males that does not necessarily occlude the leakage of urine and is not highly cumbersome to the user.

SUMMARY

The present disclosure relates to devices for management of male urinary incontinence, particularly for collecting small amounts of urine discharged between normal voiding. The present disclosure further relates to methods associated with the devices, including methods of use and manufacture. In one aspect of the present disclosure, the devices include male external urinary catheters that have an absorbent suitable for absorbing the small amounts of urine discharged between normal voiding.

A variety of examples of desirable device features or methods are set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practicing various aspects of the disclosure. The aspects of the disclosure may relate to individual features as well as combinations of features. It is to be understood that both the foregoing general description and the following detailed description are explanatory only, and are not restrictive of the claimed invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an enlarged cross sectional view of an external urinary catheter of the present invention shown in a pre-use orientation;

FIGS. **2** through **5** are cross sectional views of embodiments of the invention that have absorbent material in a distal end of the external urinary catheter;

FIGS. **6** through **8** are cross sectional views of embodiments of the invention that have absorbent material in a reversibly joined receptacle of the external urinary catheter;

FIGS. **9** and **10** are cross sectional views of embodiments of the invention that also include a semi-permeable barrier;

FIG. **11** is a cross sectional view of an embodiment of the invention that has the absorbent material adhered to an inner surface of a tubular sheath;

FIG. **12** is a cross sectional view of an embodiment of the invention that has the absorbent material adhered to the inner surface of the receptacle;

FIG. **13** is a perspective view of the external urinary catheter of FIG. **1** shown when the catheter is partially unrolled onto a penis;

FIG. **14** is a perspective view of the external urinary catheter of FIG. **13** shown when the catheter is fully unrolled onto the penis;

FIG. **15** is a side view of a mandrel used to form the tubular sheath of the external urinary catheter of the present invention;

FIG. **16** is a partial cross-sectional view of the mandrel of FIG. **15** shown when partially coated with a silicone coating;

FIG. **17** is a view similar to FIG. **16**, but after the mandrel is partially coated with an adhesive layer;

FIG. **18** is a view similar to FIG. **17**, but after a portion of the silicone coating and the adhesive layer on the mandrel have been stripped away;

FIG. **19** is a view similar to FIG. **18**, but after a first overcoat layer of silicone rubber solution has been coated on the mandrel over the adhesive layer and silicone coating remaining on the mandrel;

FIG. **20** is a view similar to FIG. **19**, but after an application of a second overcoat layer of a silicone rubber solution to a portion of the mandrel;

FIG. **21** is a view similar to FIG. **20**, but after a step of curing or vulcanizing the tubular sheath, and showing an upper portion of the tubular sheath of the external urinary catheter rolled up;

FIG. **22** is a schematic illustration of a mechanized system used to coat the mandrels, as shown in FIGS. **15-21**;

FIG. **23** is an enlarged cross-sectional view of the upper portion of the external urinary catheter of FIG. **1** in the pre-use orientation;

FIG. **24** is a top plan view of yet another embodiment of an external urinary catheter of the present invention; and

FIG. **25** is a side view of a portion of the external urinary catheter of FIG. **24**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference will now be made in detail to various features of the present disclosure that are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

I. Structural Description, Generally

Referring to FIG. **1**, one embodiment of an external urinary catheter **100** is illustrated. The external urinary catheter **100** generally includes a tubular sheath **110**, an adhesive layer **115**, and absorbent material **120**.

Following manufacture and during pre-use storage, the external urinary catheter **100** will generally have a pre-use orientation, as shown in FIG. **1**. In the pre-use orientation, an

upper portion **150** of the tubular sheath **110** is rolled up as shown. The tubular sheath **110** of the catheter **100** has an inner surface **112** and an outer surface **114**. When the upper portion **150** is rolled up in the pre-use orientation, the inner surface **112** contacts the outer surface **114** of the tubular sheath **110**.

The adhesive layer **115** of the external urinary catheter **100** is provided on the inner surface **112** of the tubular sheath **110** during manufacture. Typically, the adhesive layer **115** includes a biocompatible adhesive. A biocompatible adhesive is an adhesive that can contact skin for extended periods without irritating or damaging the skin. Typically, the adhesive layer **115** is non-releasably bonded to a bonding region **152** of the inner surface **112**, as will discussed in greater detail hereinafter. "Non-releasably bonded", "non-releasable adherence", or "non-releasable contact" refers to contact that does not permit easy separation of the adhesive layer **115** from the bonding region **152** of the tubular sheath **110**.

When the external urinary catheter **100** is in a pre-use orientation, the adhesive layer **115** is non-releasably bonded to the bonding region **152** of the inner surface **112**, and releasably bonded to the outer surface **114** of the tubular sheath **110**. "Releasably bonded", "releasable adherence", or "releasable contact" refers to contact that permits a relatively easy separation of the adhesive layer **115** from the outer surface **114** of the tubular sheath **110**. The adhesive layer **115** releases and separates from the outer surface **114** of the tubular sheath **110** when the upper portion **150** of the sheath **110** is unrolled, while the adhesive layer **115** remains non-releasably adhered to the bonding region **152** of the tubular sheath **110**.

Still referring to FIG. **1**, the absorbent material **120** of the external urinary catheter generally functions to absorb leaked or discharged urine. As will be described in greater detail hereinafter, the absorbent material **120** can either be attached to tubular sheath **110** or simply contained within the tubular sheath **110**. In embodiments that simply contain the absorbent material **120**, it is contemplated that the absorbent material can be replaced or exchanged by the user without utilizing a different tubular sheath **110**.

General examples of suitable absorbent material include, but are not limited to: cotton fiber, cellulose fiber, absorbent polymers, hydrophilic absorbing power (powders having a chemical structure that hold moisture either intermolecularly or intramolecularly), synthetic fibers, and other types of material that absorb urine.

More specific examples of cellulose fibers include wood pulp, stabilized wood pulp, wood pulp with super absorbent, peat moss board, tissue paper, or creped wadding. More specific examples of synthetic fibers include nonwoven fibers of polypropylene, polyester, nylon, polyethylene, and copolymers thereof. One example of a suitable synthetic fiber is isotactic polypropylene.

More specific examples of absorbent polymers include polypropylene, polyacrylates such as sodium polyacrylate, and copolymers thereof. Absorbent polymers formed as a foam material can also be used. Such foam materials can be formed from the water actuation of polymers based on either toluene diisocyanate (TDI) or methylene diphenyl diisocyanate (MDI), for example. Theses polymers are commercially available under, for example, the trademarks "HYPOL" (TDI) and "HYPOL PLUS" (MDI) from W. R. Grace & Co., Organic Chemicals Division (Lexington, Mass.). Polymer foams can also be formed from polyurethanes or polyolefins.

The external urinary catheter **100** of the present disclosure may include various volumes or amounts of the absorbent material **120**. Generally speaking, the amount of absorbent material **120** used can be described by an actual volume of the absorbent, or by the volume of urine absorbed by the material. The amount of absorbent material **120** included depends on the type of the absorbent material and the level of urinary discharge for which the catheter **100** is designed. For example, the amount of absorbent material **120** used for men that have higher levels of urinary discharge will be greater than the amount used for men that have lower levels of urinary discharge.

In general, the absorbent material **120** functions to absorb urine collected in the tubular sheath **110**. In the embodiment shown in FIG. **1**, the absorbent material **120** is generally located in a distal end **116** of the tubular sheath **110**. There are a number of different configurations of the tubular sheaths **110** in which absorbent material **120** can be generally located in the distal end **116**. Examples of such alternative embodiments are shown in FIGS. **2-5**.

Referring now to FIGS. **2-5**, the distal end **116** of each of the tubular sheaths **110** has a different configuration. The different configurations of FIGS. **2-5** are only exemplary configurations; and other configurations are contemplated.

Referring specifically to FIG. **2**, the distal end **116** of the tubular sheath **110** has a generally square shape with a cross-sectional dimension D**1**. The cross-sectional dimension D**1** is approximately equal to a diameter D**2** of a main portion **154** of the tubular sheath **110**. In an alternative embodiment, the cross-sectional dimension D**1** can be larger or smaller than the diameter D**2** of the remainder of the tubular sheath **110**.

In FIG. **3**, the distal end **116** of the tubular sheath **110** has a generally rounded shape with a maximum diameter D**3**. The maximum diameter D**3** is approximately the same as that of the main portion **154** of the tubular sheath **110**. In FIG. **4**, the distal end **116** has a generally round shape with a maximum diameter D**4**. The maximum diameter D**4** is greater than that of the main portion **154** of the tubular sheath **110**.

In FIG. **5**, the distal end **116** has a generally round shape with a maximum diameter D**5** that is also greater than the diameter D**2** of the main portion **154** of the tubular sheath **110**. However, in FIG. **5**, the distal end **116** includes a necked portion **156** that reduces in diameter prior to expanding to the maximum diameter D**5**. In an alternative embodiment, the tubular sheath **110** can include a necked portion that expands to a maximum diameter D**5** that is less than the diameter D**2** of the main portion **154**. It should also be understood that any combinations of these and other distal end constructions and shapes could be utilized. For example, the distal end **116** can have a necked portion, and include a generally square shape with a dimension greater than or less than the main portion **154** of the tubular sheath **110**.

Referring now to FIGS. **6-8**, in alternative embodiments, the absorbent material **120** can be located in a receptacle **122** (e.g. a pouch or cartridge). (See also FIG. **24**.) Typically, the receptacle **122** is interconnected to the distal end **116** of the tubular sheath **110** by a joining assembly **124**.

The receptacle **122** can be fashioned from a material that is one or more of pliable, durable, collapsible, and inexpensive. For example, the receptacle **122** can be pliable so that the catheter **100** is more malleable and comfortable for a user. The receptacle **122** can be durable to limit the possibility of the receptacle **122** being pierced or ruptured. The receptacle **122** can be inexpensive so that the receptacle **122** can be replaced whenever appropriate without excessive cost. Examples of suitable materials that can be used to manufacture the receptacle **122** include, for example, polyvinyl chloride (PVC), polyurethane, block copolymers such as kraton, high density polyethylene, low density polyethylene, and silicone rubber. As can be understood, the receptacle **122** is in certain embodiments waterproof (i.e., not permeable to water over the length of time that the receptacle will remain in the

user's undergarment). The material can have a waterproof quality, or a waterproofing material can be applied during the manufacture of the receptacle **122**.

Generally, the thickness of receptacle **122** (i.e., the dimension that would be shown in a side view of FIG. **6-8**) varies depending on the type of material used, and the type and amount of absorbent material **120** used. Typically, the thickness of receptacle **122**, including the absorbent material **120**, ranges from about 0.125 inches to about 1.50 inches; more typically between about 0.125 inches and 0.750 inches. Preferably, the thickness of the receptacle **122** is sized to be comfortable and concealable.

The capacity of the receptacle **122** varies depending on the level of urinary discharge for which the specific embodiment is designed. Embodiments designed for higher levels of urinary discharge will have receptacles **122** with a higher capacity, while those designed for lower levels of urinary discharge will have receptacles **122** with a lower capacity. The capacity of the receptacles **122** can be smaller than a leg bag and suitable for receiving discharge between voiding. Typically, the receptacle **122** has a capacity or volume V from about 25 mL to about 100 mL. Generally speaking, if the receptacle **122** is designed for higher levels of urinary discharge, the receptacle has a volume V of about 40 to 100 mL. If the receptacle **122** is designed for lower levels of urinary discharge, the receptacle has a volume V of about 25 to 35 mL.

The shape of receptacle **122** can vary. Exemplary configurations of the receptacle **122** are illustrated in FIGS. **6-8**. As shown, the receptacle **122** can have virtually any shape, including a generally round shape (FIGS. **6** and **7**) and a generally square shape (FIG. **8**).

Embodiments that include the receptacle **122** can be designed so that receptacles of variable capacity can be used interchangeably. This feature allows a user to vary the capacity of the external urinary catheter **100** based on a personal level of urinary discharge, which may or may not vary. For example, in one embodiment, a kit may be provided to a user. The kit may include a tubular sheath **110** along with an array of receptacles **122**. Each receptacle provided would include a different amount of absorbent material contained within the receptacle. This would permit the user to adjust the capacity of the external urinary catheter **100** according to the daily needs of the user.

In use, discharged urine flows from the sheath **110**, through the joining assembly **124**, and into the receptacle **122**. The joining assembly **124** of the external urinary catheter **100** functions to reversibly join the receptacle **122** to the distal end **116** of the tubular sheath **110**. What is meant by "reversibly join" is that the receptacle **112** sealingly attaches to the tubular sheath **110**, yet is detachable or removable from the sheath without causing damage to the sheath.

The joining assembly **124** is sized and constructed such that the receptacle **122** is located a distance near the distal end **116** of the tubular sheath **110**, as opposed to a leg bag which is located a distance away from the tubular sheath **110**. Typically, the receptacle **122** is located in relation to the tubular sheath **110** such that the entire catheter **100**, including the receptacle **122**, is located at and within the pelvic region of the user. That is, the tubular sheath **110**, the joining assembly **124**, and the receptacle **122** can all fit within a user's undergarment at the urinary area. The user is thereby not encumbered with routing tubes through the undergarment to locations away from the urinary area, such as is required by conventional leg bags, for example. In the illustrated embodiment, the receptacle **122** is located a distance D**6** (e.g. FIG. **8**) of about one inch to about three inches from the distal end **116** of the tubular sheath **110**.

In the embodiment of FIG. **6**, the joining assembly **124** includes a female connector **158** extending from the distal end **116** of the tubular sheath **110**, and a male connector **160** extending from the receptacle **122**. In the embodiment of FIG. **7**, the female connector **158** of the joining assembly **124** extends from the receptacle **122**, and the male connector **160** extends from the distal end **116** of the tubular sheath **110**. In each embodiment, the male connector **160** fits within the female connector **158** so that the tubular sheath **110** is reversibly joined to the receptacle **122**.

In another embodiment, the joining assembly **124** can include a lock and unlock feature so that receptacle **122** is more securely reversibly joined to tubular sheath **110**. In yet another embodiment, the joining assembly **124** functions like or includes a luer lock type assembly. As shown in FIGS. **6-8**, the size of joining assembly **124** can vary. For example, in FIG. **7**, the joining assembly **124** is larger than the joining assemblies shown in FIGS. **6** *and* **8**. In an embodiment, the joining assembly **124** is large enough so that urine flow into the receptacle **122** is not restricted.

Referring now to FIGS. **24** and **25**, another alternative embodiment of the external urinary catheter **100** is illustrated. Similar to some of the previous embodiments, the tubular sheath **110** of this embodiment is interconnected to the receptacle **122** via the joining assembly **124**.

As shown in FIG. **24**, the distal end **116** of the tubular sheath **110** defines an opening **166** that receives the joining assembly **124**. The joining assembly **124** provides fluid communication between the tubular sheath **110** and the receptacle **122**. The opening **166** is located in the tapering or necked portion **156** of the tubular sheath.

The joining assembly **124** in the illustrated embodiment includes a hollow fitting **130** and a tube member **140**. In an embodiment, each of the hollow fitting **130** and the tube member **140** of the joining assembly **124** is sized so that urine flow into the receptacle **122** is not restricted.

The hollow fitting **130** has first and second ends **132**, **134**. Each of the first and second ends **132**, **134** is a male fitting end. The first male fitting end **132** is sized and constructed for receipt within the opening **166** formed in the distal end **116** of the tubular sheath **110**. In the illustrated embodiment, the first male fitting end **132** includes ridges **138** that taper to ease insertion and removal of the fitting **130** into and from the opening **166**. Other embodiments may include a first end **132** that continuously tapers without ridges, or that has a straight fitting construction.

The second male fitting end **134** is received within a first end **142** of the tube member **140**. In the illustrated embodiment, the second male fitting end **134** is secured within the first end **142** of the tube member **140** by an adhesive or other securing material or construction. In the illustrated embodiment, the second male fitting end **134** is a straight fitting end. Other embodiments may include a second end **134** that continuously tapers or includes ridges.

A second end **144** of the tube member is positioned within an opening **90** formed in the receptacle. In the illustrated embodiment, the second end **144** of the tube member **140** is secured within the opening **90** of the receptacle **122** by an adhesive or other securing material or construction.

In the embodiment shown in FIGS. **24** and **25**, the receptacle **122** is constructed from a material that is pliable and durable, such as PVC, for example. In particular, first and second sheets or plies **168**, **170** of the material are joined together to form an interior **172** for receipt of the absorbent material **120**. In one embodiment, the two plies may be sewn together along a seam **102**, or adhered together along the seam. The PVC receptacle **122** also has sufficient pliability so

that the catheter **100** is more malleable and more comfortable for a user. In addition, the PVC receptacle **122** is durable to limit the possibility of the receptacle **122** being pierced or ruptured. Further, the PVC receptacle has moisture impermeable qualities that contain moisture absorbed by the absorbent material **120** within the interior **172** of the receptacle **122** so that the exterior of the receptacle **122** remains dry.

As shown in FIGS. **24** and **25**, the receptacle **122** generally has a width W, a height H, and a thickness T, although the disclosed principles can be applied in a variety of sizes and applications. The width W of the receptacle **122** can be, for example, between 1.5 and 5.0 inches or between about 2.0 and 3.0 inches. The height H of the receptacle **122** can be, for example, between 2.0 inches and 6.0 inches or between about 3.0 and 4.0 inches. The thickness T of the receptacle **122** is generally between 0.125 inches and 1.50 inches, depending upon the type of absorbent material **120** used. In an embodiment, the thickness T is between about 0.5 and 1.0 inches. Further, the distance D**6** (see FIG. **6**) between the receptacle **122** and the distal end **116** of the tubular sheath **110** when assembled (not shown) can be between 2.0 inches and 6.0 inches; e.g., between about 3.5 and 4.5 inches.

Each of the width W, the height H, the thickness T, and the distance D**6** are sized and dimensioned such that the receptacle **122** conveniently fits within the undergarment of the user. That is, the receptacle **122** is sized so that the entire catheter **100** fits within the user's underwear, and does not required that the receptacle be attached or located at a location away from the pelvic area of the user. Accordingly, the PVC material of the receptacle **122** is also chosen to be comfortable against the user's skin. For example, the exterior of the receptacle **122** can be flocked with cotton or synthetic flocking, or embossed. As previously discussed, the shape of receptacle **122** can vary. In the embodiment of FIGS. **24** and **25**, the receptacle **122** has a rectangular configuration, although any shape that comfortably fits an average-sized male can be used.

At the same time, the receptacle **122** is sized to provide a urine absorbing capacity depending on the level of urinary discharge between normal voiding. As previously described in relation to the other embodiments, the capacity of the receptacle **122** of FIG. **24** can be smaller than a leg bag and suitable for receiving discharge between voiding. The width W, height H, and thickness T of the receptacle **122** defines a volume associated with the receptacle **122**. The capacity of the receptacle **122** is a function of the volume and the type of absorbent material **120** used. In an embodiment, the volume of the receptacle **122** is between 1.0 cubic inch and 5.0 cubic inches. In one embodiment, the absorbent material **120** is cellulose fiber. In providing cellulose fiber absorbent material in the volume of between about 3.0 and 4.0 cubic inches, the receptacle **122** has a capacity to contain between about 45 and 60 mL of urine. Because the receptacle **122** is sized to fit within the user's pelvic region, (i.e., within the user's undergarment) the capacity of the receptacle **122** is typically no more than about 100.0 mL.

Similar to the previous embodiments, the embodiment of FIG. **24** is designed so that the receptacle **122** can be interchanged. This feature allows a user to vary the capacity of the external urinary catheter **100** based on a personal level of urinary discharge, which may or may not vary. For example, a user may interchange a first receptacle with a second receptacle having a different amount of absorbent material or a different type of absorbent material to adjust the capacity of the external urinary catheter **100**.

The receptacle **122** is also interchangeable so that a user can replace a filled or used receptacle with a new receptacle as needed. For example, during use of the catheter **100** embodiment of FIG. **24**, urine discharged into the sheath **110** flows through the joining assembly **124** and into the receptacle **122**. When the receptacle **122** has filled, the user detaches the filled receptacle by removing the first end **132** of the fitting **130** from the opening **166** in the tubular sheath **110**. The tubular sheath **110** remains in position on the penis. A new receptacle is then attached to the distal end **116** of the tubular sheath.

The joining assembly **124** of the external urinary catheter **100** functions to reversibly join the receptacle **122** to the distal end **116** of the tubular sheath **110**. In the embodiment of FIG. **24**, the joining assembly **124** attaches and detaches from the tubular sheath **110** (i.e., the joining assembly **124** is removed or detached along with the receptacle **122**). In an alternative embodiment, the catheter **100** can be constructed such that the receptacle **122** attaches and detaches from the joining assembly **124** (i.e., only the receptacle **122** is removed or detached).

The receptacle **122** can also be disposable. The user may simply throw away the receptacle when the receptacle has been filled. In alternative embodiments, the receptacle **122** may be recycled. That is, the receptacle can be configured to provide access to the absorbent material **120** so that used absorbent material can be removed and replaced with new material, and the receptacle **122** reused.

Various alternative embodiments including other features can be practiced in accord with the principles disclosed. For example, the external urinary catheter **100** may include more than one type of absorbent material **120**. For instance, a synthetic fiber such as polypropylene, polyester, nylon, polyethylene, or copolymers thereof can be spunbound to create a coverstock for another absorbent. A coverstock functions to provide a semi-permeable membrane or barrier that allows moisture to pass through that barrier so that the moisture is absorbed by another absorbent material enclosed within the barrier. Use of a coverstock provides a number of advantages, including keeping the skin of the user more dry, and retaining the absorbent material **102** in a particular location, such as a distal end **116** of the tubular sheath **110**. Suitable examples of synthetic fibers that can be spunbound to form coverstock include polyester and polypropylene.

Referring now to the external urinary catheters **100** of FIGS. **9** and **10**, two embodiments of a coverstock or semi-permeable barrier **126** are illustrated. In the embodiment of FIG. **9**, the semi-permeable barrier **126** is located adjacent to the distal end **116** of the tubular sheath **110**. In the embodiment of FIG. **10**, the semi-permeable barrier **126** is in the joining assembly **124**.

The semi-permeable barrier **126** functions to allow urine to pass into the absorbent material **120**, but does not allow the absorbent material **120** to migrate through to the main portion **154** of the tubular sheath **110**. Alternatively, or in addition, the semi-permeable barrier **126** can function to allow urine to pass through into the volume V containing the absorbent material **120**, but does not allow urine to pass out of the volume V. In an embodiments in which the absorbent material **120** is completely contained or surrounded by the barrier **126**, the barrier **126** and the absorbent material **120** can be replaced or exchanged by the user without utilizing another tubular sheath **110**. For example, as shown in FIGS. **13** *and* **14**, the barrier **126** and absorbent material **120** can be provided in the form of a packet **118**. The packet **118** can be replaced and exchanged without utilizing another tubular sheath **110**. It is to be understood that the semi-permeable barrier can be incorporated into any of the embodiments shown, and in combination with any other features described.

Another alternative embodiment including another feature that can be practiced in accord with the principles disclosed is illustrated in FIG. **11**. In this embodiment the absorbent mate-

rial **120** of the external urinary catheter **100** is adhered to the inner surface **112** of the tubular sheath **110**. Adhering the absorbent material **120** to the inner surface **112** prevents the absorbent material **120** from migrating within the tubular sheath **110**. Methods of adhering the absorbent material **120** to the inner surface **112** of the tubular sheath **110** vary depending on the composition of the absorbent material **120**. The absorbent material **120** can also be adhered to the inner surface of the receptacle **122**, as shown in FIG. **12**. It is to be understood that adhering the material to an inner surface can be incorporated into any of the embodiments shown, and in combination with any other features described.

II. Method of Use

The external urinary catheter **100** is typically worn by users that discharge relatively small amounts of urine between normal voiding, as compared to users that discharge an amount that necessitates a leg bag. Referring to FIGS. **13** and **14**, in use, a user, or perhaps a health care professional, engages a tip **31** of a penis **30** with the external urinary catheter **100** in the pre-use orientation (shown in FIG. **1**). In particular, the distal end **116** of the tubular sheath **110** is applied to the tip **31** of the penis **30**. The upper portion **150** of the tubular sheath **110** is then unrolled using moderate force to press the rolled up portion of the upper portion **150** in a direction away from the tip **31** of the penis **30**. This can generally be accomplished by pressing on the rolled upper portion **150** with one's thumb and forefinger (not shown).

As the upper portion **150** unrolls, the adhesive layer **115** releases from the outer surface **114** of the tubular sheath **110**. In an embodiment, the releasability characteristics are such that the upper portion **150** is relatively easy to unroll onto the penis **30**. As the adhesive layer **115** comes into contact with an outer surface **32** of the penis **30**, the adhesive layer **15** adheres to the outer surface **32**. This secures the external urinary catheter **100** to the penis **30**. In an embodiment, the adhesive layer **115** seals the tubular sheath **110** to the penis **30** such that leakage above the area where the adhesive layer **115** contacts the outer surface **32** of the penis **30** is prevent. The external urinary catheter **100** secures to the user only at the location where the adhesive layer **115** contacts the outer surface **32** of the penis. No other belts, straps, garments, or coupling/attaching devices are necessary. The catheter **100** of the present invention thereby provides a more comfortable solution to incontinence, and is not highly cumbersome or bulky for the user.

The external urinary catheter **100** can be removed from the penis **30** by pulling the upper portion **150** of the tubular sheath **110** away from the penis **30** and down over the outer surface **114**. Removal can be accomplished in any manner that accommodates the comfort of the patient. It will be appreciated that one appropriate method of removing the catheter **100** is to roll the upper portion **150** up again so that the catheter **100** returns to generally the same orientation as that shown in FIG. **1**. When removing the catheter **100**, the adhesive layer **115** releases the outer surface of the penis **30**, and the catheter **100** can be removed from the penis **30** with relative ease.

Generally speaking, the external urinary catheter **100** can be worn for variable amounts of time depending on the user, the capacity for which the device is designed, and the amount of urinary discharge the user is experiencing. For example, the external urinary catheter **100** can be worn for certain defined periods of time, until the catheter begins to feel uncomfortable, until the absorbent has reached an absorbance capacity, or until the user removes the catheter to void.

Depending on the specific absorbent material **120** utilized, the catheter **100** may exhibit altered characteristics when the material has absorbed an amount of urine. Examples of such altered characteristics include an increase in the weight of the catheter **100** and a change in the flexibility of the portion of the catheter **100** that contains the absorbent material **120**. In certain embodiments, the absorbent material can change color to indicate that material is saturated with urine. Changes such as these and others can also be used by the wearer to determine when the catheter **100** should be removed and/or replaced.

In addition, in embodiments having a detachable receptacle **122** (e.g., FIG. **24**), the tubular sheath **110** can be worn throughout the day, not only between voiding. In particular, the receptacle **122** can be detached when the user needs to void. The user can then void through the open end **166** of the tubular sheath **110**, and then reattach the receptacle **122** or reattach a replacement receptacle to the same tubular sheath **110**.

III. Method of Manufacturing

As described herein below, the tubular sheath **110** can be made by combining two or more layers of a silicone rubber solution or of separate silicone rubber solutions. Once the silicone rubber solutions are dried and cured in a vulcanizing process, the respective silicone rubber solution coatings combine to form a single unitary tubular sheath without separate layers. It will be appreciated that any silicone rubber solution used to form silicone rubber products of one type or another may be used to form the silicone rubber sheath of the present invention. The vulcanizing process may be either a heat process, a catalyzed process employing a catalyzing agent or agents, a combination of the two, or any other suitable vulcanizing process known in the art.

Referring now to FIGS. **15-22**, a suitable method of making an external urinary catheter **100** of the present invention includes a series of steps designed to coat a mandrel **20**. The mandrel **20** has a generally cylindrical shape, which may narrow or taper at a lower end **22** (FIG. **15**). In one embodiment, the lower end **22** of mandrel **20** may include a larger diameter than that of the remaining mandrel **20**. The mandrel **20** having a larger lower end diameter may be utilized to form a bulbous portion **162** at the distal end **116** of the tubular sheath **110**, such as shown in FIG. **4**. Alternatively, the lower end **22** of mandrel **20** may be configured to provide the embodiments shown in FIGS. **2**, **3**, and **5**. In certain embodiments, either the external surfaces **164** of the mandrel **20** are coated with Teflon®, or the mandrel **20** is made of Teflon®. A tip (not shown) for forming male or female connectors **158**, **160** (FIGS. **6** and **7**) of the joining assembly **124** can be coupled to the lower end **22** of the mandrel **20**.

In an embodiment, depicted in FIG. **22**, a series of mandrels **20** are attached to a pallet **23** so that numerous external urinary catheters **100** can be mass-produced. This can be accomplished by coating each of the mandrels **20** in a series of coating steps. The coating steps include dipping each of the mandrels **20**, e.g., in unison, in a series of dip tanks **80***a-e* that are raised up to a precise level calculated to accomplish a specific task. It will be appreciated that a series (not shown) of pallets can also be employed so that a continuous mechanized production operation can be developed to mass-produce catheters **100**. The pallet **23** or a series of pallets (not shown) are advanced by a mechanized advancing system **88**. It will be appreciated that any known mechanization system for advancing the pallet **23** or pallets can be used.

Referring now to FIGS. **16** and **22**, in one method of manufacture, a first portion **24** of the mandrel **20** is coated with a silicone coating **40**. The first portion **24** of the mandrel **20** is defined as the area of the mandrel between dashed lines A and B illustrated in FIG. **16**. To create the silicone coating **40**, the

pallet **23** of mandrels **20** is dipped into a first dip tank **80***a* containing a fluid silicone release agent **81**, e.g., a polydimethylsiloxane fluid (Dow Coming 360 Medical Fluid from Dow Corning, Inc., Midland, Mich. 48360) having a viscosity of 12,500 centistokes, diluted about 1:25 in hexamethyldisiloxane. The fluid silicone release agent **81** forms the silicone coating **40**. In order to ensure that the first portion **24** (FIGS. **16-18**) of the mandrel **20** is completely coated with the silicone coating **40**, the pallet **23** to which the mandrels **20** are attached is centered over the first dip tank **80***a* and the dip tank **80***a* is raised a calculated distance, as shown. The distance is calculated such that the mandrel **20** is submersed within the release agent **81** to a designated level corresponding to the dashed line A. At the designated level, the entire first portion **24** of mandrel **20** is submersed. After the first portion **24** is fully submersed, the first dip tank **80***a* is lowered and the silicone coating **40** is permitted to dry (FIG. **16**).

Referring now to FIGS. **17** and **22**, the pallet **23** is then advanced to a second dip tank **80***b* containing adhesive material or fluid **82**. The adhesive material **82** bonds to unvulcanized silicone rubber during a vulcanizing process. The adhesive material **82** can include a suitable polymeric adhesive, such as a suitable copolymer of acrylic acid esters with vinylacetate, or cross linking pressure sensitive adhesive, for instance. One example of an adhesive that can be used is Gelva MAS 788 manufacture by Solutia Inc. (St. Louis Mo.). The second dip tank **80***b* is raised a distance (not shown) calculated to dip the mandrel **20** into the adhesive fluid **84** in the second dip tank **80***b* so that the entire first portion **24** of the mandrel **20** between the lines designated A and B is coated by the adhesive fluid **82**. As shown in FIG. **17**, the adhesive fluid **82** forms the adhesive layer **115**, which is disposed over the silicone coating **40**. The second dip tank **80***b* is then lowered, and the adhesive layer **115** allowed to dry for a period of time.

Referring now to FIGS. **18** and **22**, the pallet **23** is then advanced to a third dip tank **80***c* containing a solvent **83**, e.g., trichloroethane (trichlor 1,1,1) or xylene. The solvent **83** strips or removes the adhesive layer **115** and the silicone coating **40** from the mandrel **20**. In this step, the dip tank **80***c* is raised a distance (not shown) calculated to dip the mandrel **20** into the solvent **83** up to the line on the mandrel **20** designated B so that the adhesive layer **115** and the silicone fluid coating **40** which coat a second portion **26** of the mandrel **20** is stripped. The second portion **26** of the mandrel **20** is defined as the area of the mandrel below the line designated B, and proximate the lower end **22** of the mandrel **20**. In some methods, the tank **80***c* may be lowered and raised several times to provide a rapid stripping action. The pallet **23** can also be advanced to a new dip tank (not shown) having a second solvent (not shown) to further assist in stripping the second portion **26** of the mandrel **20**. In some embodiments, a vibrator (not shown) is connected to the pallet **23** or the mandrel **20** to vibrate the mandrel **20** and speed the removal of the adhesive coating **115**. In other embodiments, an ultrasonic cleaning system (not shown) is incorporated into the dip tank **80***c*.

In some methods, a further step can be added at this point in the manufacturing process. This step involves shaping the lower end **22** of mandrel **20** by selectively coating the lower end **22** with an agent that buildups the lower end **22**. Shaping the lower end **22** of the mandrel **20** provides the shaped distal end **116** configurations of the catheter **100** previously disclosed. The agent can be the same or similar to that of the mandrel release agent **81** utilized previously.

In continuing the manufacture of the catheter **100**, the mandrel **20** is advanced on the pallet **23** to a fourth dip tank **80**d containing an unvulcanized silicone rubber solution **84** which can be a disiloxane solvent, e.g., a hexamethyldisiloxane solvent. The disiloxane solvent is suitable because the disiloxane solvent does not destroy the integrity of the adhesive layer **1715** that remains on the first portion **24** of the mandrel **20**. When the mandrel **20** is dipped into the silicone rubber solution **84** in the fourth dip tank **80***d*, the silicone rubber solution **84** coats the mandrel **20** and overcoats the silicone coating **40** and the adhesive layer **115**. This overcoating forms a first overcoat layer **46** as shown in FIG. **19**. If the shaping step was performed, the first overcoat layer **46** will have a shaped region, such as an enlarged region, that eventually becomes the distal end **116** of the tubular sheath **110**. The fourth dip tank **80***d* is then lowered, and the overcoat layer **46** is allowed to dry for a period of time.

Referring now to FIGS. **20** and **22**, the pallet **23** is then advanced to a fifth dip tank **80***e* containing an additional silicone rubber solution **85**. The additional silicone rubber solution **85** can have a greater concentration of silicone rubber than the first overcoat layer **46**. The solvent may also be varied. The dip tank **80***e* is raised and the mandrel **20** is dipped into the dip tank **80***e* to a level just below the line designated B so as to add an additional thickness proximate the lower end **22** of the mandrel **20**. This forms a final overcoat layer **48** over the first overcoat layer **46**. The dip tank **80***e* is then lowered and the final overcoat layer **48** is allowed to air dry so that the solvent in the silicone rubber overcoat layer **48** evaporates. It will be appreciated that additional dip tanks may be provided for additional dipping steps.

In one embodiment, the first overcoat layer **46** has a generally uniform thickness through out the construction of the sheath **110**. The thickness is typically between about 0.002 and 0.010 inches; e.g., between about 0.003 and 0.008 inches. The final overcoat layer **48** provides additional thickness in the proximal region **116** of the sheath **110**. The thickness at the distal end **116** is between 0.020 to 0.080 inches; e.g., between about 0.030 to 0.060 inches.

In an embodiment of the method, the final overcoat layer **48** is vulcanized or cured in an oven (not shown) at an elevated temperature, e.g., about 205° F. It will be appreciated that the temperature is maintained at a level below the boiling point of the solvents of the silicone rubber solutions to prevent the formation of bubbles in the silicone rubber caused by evaporation or the boiling off of the solvents. Furthermore, it will also be appreciated that other silicone rubber systems that are catalyzed without heat may also be used to provide a vulcanizing system resulting in a vulcanized silicone rubber elastomeric construction **50**.

Once the silicone rubber has been vulcanized, the tubular sheath **110** is formed. The tubular sheath **110** is permitted to cool. When cooled, the upper portion **150** of the tubular sheath is rolled from a top **25** of the mandrel **20** (FIG. **21**) so that the inner surface **112** (FIG. **23**) of the tubular sheath **110** rolls up onto the outer surface **114** of the tubular sheath. In the process of rolling the tubular sheath **110**, the adhesive layer **115**, which has now been integrally bonded with the silicone rubber during the vulcanizing process, comes into contact with the outer surface **114** of the tubular sheath **110**.

Referring to FIG. **23**, when the catheter **100** is fully rolled up into its pre-use orientation (as shown in FIG. **1**), the catheter **100** includes the single tubular sheath **110** (FIG. **1**) having a unitary construction made of silicone rubber with an adhesive layer **115** integrally bonded to the tubular sheath **110**. The adhesive layer **115** is interposed between the inner surface **112** and the outer surface **114** of the sheath **110**. The adhesive layer **115** is integrally bonded to the inner surface **112** as a result of cross-linking between constituents in the adhesive layer **115** and constituents in the unvulcanized sili-

cone rubber of the overcoat layer **46** during the vulcanizing process. The adhesive layer **115** will not, however, irreversibly adhere or bond to any of the vulcanized silicone rubber surfaces with which the adhesive contacts after the vulcanizing process. The adhesive layer **115** does contact the outer surface **114**, but any adherence to the outer surface **114** is limited to releasable adherence.

In particular, when the upper portion **150** of the tubular sheath is rolled up, trace amounts of the silicone coating **40** adhere to the adhesive layer **115**, and the remaining portion of the silicone coating **40** stays on the mandrel **20**. The trace amounts of silicone coating **40** that adhere to the adhesive strip are absorbed by the outer surface **114** of the tubular sheath **110** when the coating **40** comes into contact with the outer surface **114**.

It is to be appreciated that it is important that the trace amounts of silicone fluid adhering to the adhesive layer **115** are absorbed by the outer surface **114**, because if not absorbed, the coating **40** could interfere with the adherence of the adhesive layer **115** with the penis **30**. It will also be appreciated that the silicone coating **40** is just one of many mandrel release agents which can be used to coat the mandrel **20**. Other agents that prevent making removal of the adhesive layer **115** from the mandrel **20** overly difficult can also be used.

The adhesive layer **115** is selected for its ability to bond with the silicone rubber during the vulcanized process and for its lack of adherence when the layer **115** comes into contact with vulcanized silicone rubber after the vulcanizing process. It will be appreciated that any biocompatible adhesive which will cross-link with silicone rubber during the vulcanizing process will be a suitable adhesive so long as the biocompatible adhesive will releasably adhere to new silicone rubber surfaces with which the biocompatible adhesive comes into contact after the adhesive is bonded to the inner surface of a silicone rubber sheath during the vulcanizing process.

Inclusion of the absorbent material **120** occurs after the above formation of the tubular sheath **110**. The specific method of providing or including the absorbent material **120** depends on the specific type of the absorbent material **120** used, and the specific arrangement. For example, in the embodiments having the absorbent material **120** located in the distal end **116** of the sheath **110**, the absorbent material **12** is typically placed at or adjacent to an enclosed tip **53** (FIG. **21**) of the sheath **110**. For instance, if the absorbent material **120** is hydrophilic powder, the material can simply be introduced into the tubular sheath **110**, and directed towards the enclosed tip **53** at the distal end **116** of the sheath **110**. If the hydrophilic powder is to be adhered to the inner surface **112** of the tubular sheath **110**, a suitable adhesive, such as Gelva Mas 788, for example, can be applied to the desired portion of the tubular sheath **110** adjacent the enclosed tip **53** before the powder is introduced into the tubular sheath **110**.

In the embodiments having the absorbent material **120** located in the receptacle **122**, the enclosed tip **53** of the tubular sheath **110** is removed to provide the opening **166** (FIG. **24**) at the distal end **116**. The absorbent material **12** is disposed in the receptacle **122**, and the receptacle is interconnected to the opening **166** at the distal end **116** via the joining assembly **124**.

The above specification provides a complete description of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, certain aspects of the invention reside in the claims hereinafter appended.

We claim:

1. An external urinary catheter, comprising:

a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;

a layer of adhesive material for securing the tubular sheath to a user at a location during use, the layer of adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath;

a receptacle detachably interconnected to a distal end of the tubular sheath, the receptacle defining an interior in which urinary discharge is collected; and

an absorbent material disposed within the interior of the receptacle to absorb the urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock;

wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath, and wherein the receptacle is sized such that the receptacle resides within a user's pelvic region when the catheter is worn.

2. The catheter of claim **1**, wherein the absorbent material includes cellulose fiber.

3. The catheter of claim **1**, further including a joining assembly positioned between the distal end of the tubular sheath and the receptacle, the joining assembly providing fluid communication between the tubular sheath and the receptacle.

4. The catheter of claim **3**, wherein the joining assembly is detachably interconnected to the distal end of the tubular sheath.

5. The catheter of claim **3**, wherein the joining assembly includes a fitting sized for receipt within an opening formed in the distal end of the tubular sheath, the fitting and receptacle being detachable from the opening of the tubular sheath.

6. The catheter of claim **1**, wherein the interior volume of the receptacle is sized to collect no more than 100 mL of urine.

7. The catheter of claim **1**, wherein the interior volume of the receptacle is between about 1.0 and 5.0 cubic inches.

8. The catheter of claim **1**, wherein the receptacle has a width and a height, the width being between about 2.0 and 3.0 inches, and the height being between about 3.0 and 4.0 inches.

9. The catheter of claim **1**, wherein the catheter secures to the user only at the location contacted by the layer of adhesive material.

10. The catheter of claim **1**, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

11. The catheter of claim **1**, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

12. An external urinary catheter, comprising:

a tubular sheath of silicone rubber, the tubular sheath having an inner surface and

an outer surface, the tubular sheath further having a main portion and a bulbous distal end, the main portion being sized to receive an user's penis, the bulbous distal end being greater in diameter than the main portion of the tubular sheath;

a layer of adhesive material that secures the tubular sheath to the user's penis at a location during use, the layer of

adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath; and

an absorbent material disposed in the bulbous distal end of the tubular sheath to absorb urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock;

wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath, and wherein the entire external urinary catheter resides within a user's pelvic region when the catheter is worn.

13. catheter of claim **12** wherein the absorbent material includes cellulose fiber.

14. The catheter of claim **12** wherein the tubular sheath includes a necked portion located between the main portion and the bulbous distal end.

15. The catheter of claim **12** wherein the catheter secures to the user only at the location contacted by the layer of adhesive material.

16. The catheter of claim **12**, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

17. The catheter of claim **12**, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

18. An external urinary catheter, comprising:

a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;

a layer of adhesive material for securing the tubular sheath to a user at a location during use, the layer of adhesive material being non-releasably bonded to a portion of the inner surface of the tubular sheath;

an absorbent material disposed in relation to the tubular sheath to absorb urinary discharge, the absorbent material being contained within and surrounded by a semi-permeable coverstock; and

wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath.

19. The catheter of claim **18** wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

20. The catheter of claim **18** wherein the tubular sheath has a main portion and a distal end, the absorbent material being disposed in the distal end of the tubular sheath.

21. The catheter of claim **18** further including a receptacle attached to the distal end of the tubular sheath, the absorbent material being disposed within the receptacle.

22. The catheter of claim **18**, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

23. An external urinary catheter, comprising:

a tubular sheath of silicone rubber, the tubular sheath having an inner surface and an outer surface;

a layer of adhesive material for securing the tubular sheath to a user at a location during use;

a receptacle detachably interconnected to a distal end of the tubular sheath by a joining assembly, the receptacle defining an interior in which urinary discharge is collected, the receptacle residing within a user's pelvic region when the catheter is worn, the joining assembly including a fitting received within an opening formed in a distal end of the tubular sheath; and

an absorbent material disposed within the interior of the receptacle to absorb the urinary discharge, the absorbent material being contained within and surrounded by a semipermeable coverstock.

24. The catheter of claim **23**, wherein the fitting has a tapered end that is received within the opening of the tubular sheath.

25. The catheter of claim **23**, wherein prior to use, the inner surface of the silicone rubber sheath is rolled up upon the outer surface of the silicone rubber sheath for storage, and wherein the adhesive material bonded to the inner surface releasably contacts portions of the outer surface of the tubular sheath.

26. The catheter of claim **23**, wherein the semi-permeable coverstock permits the urinary discharge to pass through the semi-permeable coverstock to the absorbent material, and prevents the urinary discharge from migrating back through the semi-permeable coverstock to a main portion of the tubular sheath.

27. The catheter of claim **23**, wherein a packet comprises the semi-permeable coverstock and the absorbent material.

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